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MARYLAND PHARMACIST

January/February, 1996 Vol. 72, No. 1

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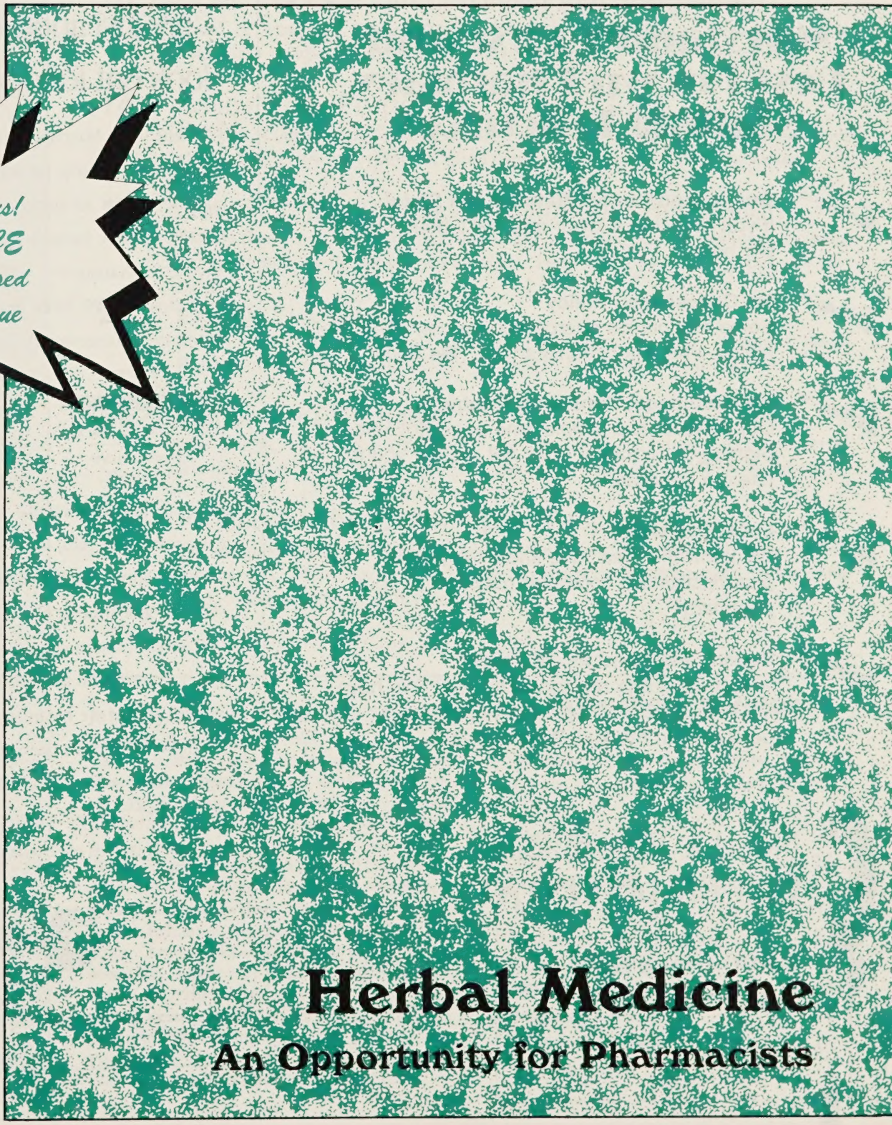

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MARYLAND PHARMACIST

The Official Publication of The Maryland Pharmacists Association

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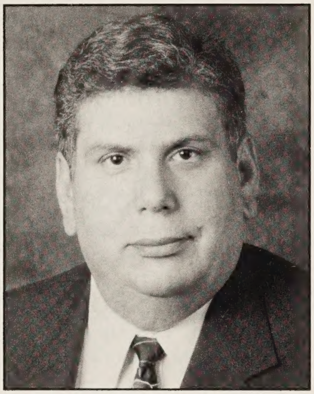
President's Commentary
Snowed Under

Okay, okay. You're probably sick of hearing about the great blizzard of 1996 by now -- that's assuming that you've managed to dig a path to your mailbox or that a snowplow has finally found its way into your neighborhood. But something struck me about how appropriate the word "blizzard" describes what's happening in pharmacy so I hope you'll humor me with a little patience.

As every news reporter was more than happy to tell us in the beginning of January, a true "blizzard" is characterized by sustained winds of more than 32 miles per hour, liberal dumping of the fluffy white stuff, "white-outs" and reduced visibility. Blizzards are deadly. Those who are either unprepared for or who are caught unaware of a blizzard's approach are at real risk of life and property.

So how's our recent meteorological experience in Maryland like pharmacy?


James Tristani, P.D.
1995-96 MPhA President

Think about the "winds" we're experiencing in pharmacy. Drastic reductions in prescription reimbursement from pharmacy benefit managers come sweeping through with little thought to the damage they cause to the infrastructure of community and institutional pharmacies. Roaring down on us is the belief that we must redesign and adapt to the concepts of pharmaceutical care immediately or we'll all be blown away. Buffeting individual pharmacists is the uncertainty of re-engineering, mergers, and layoffs and how those winds will affect our families and everything we for which we have worked. It's no wonder that so many pharmacists feel like they are literally fighting against an invisible, imperious force just to stay on their own two feet.

And let's not forget the accumulation of snow that's part and parcel of a good blizzard. One little flake by itself isn't so bad. A small flurry is pretty easy to handle, too. But when the little flakes are constantly falling, it can be overwhelming.

Doesn't this sound like filling prescriptions at the beginning of the year? Those pharmacists who worked the first week of January must have felt that every little problematic third-party prescription -- the ones with new cards, new plans, new processors, wrong birthdates, wrong provider numbers, wrong eligibility information -- were accumulating as fast as a blizzard. Taken one at a time or a few at a time was okay. But filling prescriptions became a survival skill; just keeping ahead was next to impossible.

And what about that reduced visibility? I think that's probably the most telling part of pharmacy's ongoing blizzard. We're all concentrating so hard on trying to see a foot in front of us that we're forgetting, or finding it just impossible, to try and figure out where we're trying to go. Pharmacy and pharmacists are being pulled in so many different directions at once, we've resorted to blindly plunging ahead. The problem is that we're not sure where ahead is! Are we slowly walking towards shelter and a safe place or are we stepping closer and closer to a precipice we can't even see.

If there's anything that we can learn from our recent experience with winter weather it's this: we must stop, figure out where we are headed, and then proceed slowly and steadily in that direction. And that's something that your Association's Board of Trustees is doing right now. Under the leadership of Vice-Speaker Crystal King, we are spending considerable time looking at who we are now, where we want to be, what our strengths, weaknesses, opportunities and threats are. Our goal as your leadership is to come up with a solid plan for the future of MPhA. That way, even as the snow piles up around us, we'll at least know which way we need start digging to get back on track.

Now, if you'll excuse me, I've got to go and find my shovel. **MP**

Lawful Herbal Medicine

Part One of a Two Part Series

William J. Skinner, R.Ph., J.D.

Modern man is slowly catching up to the reality that the Earth is full of wonderful natural remedies. The modern community pharmacies and chain drug stores of today and the drugstore of 19th century America are quite different from the apothecaries of Galen, Dioscordies and Paracelsus, but according to Farnsworth and Morris, in 1976, 23 percent of all modern prescriptions in the U.S. were still derived from or contained plant substances.[1] In some European countries, more so in Germany than in the Realm of Henry, the 8th's, England, human use of plant remedies seems far ahead of that by U. S. citizens. If one looks at what is spent on herbal remedies and teas around the world, the European herbal market is now larger than that in the United States by several billion dollars.[2] Herbal medical sales were estimated at $6 billion in 1993 in the Europe Common Market and only $1.5 billion in the U.S., while in Asia sales are $2.3 billion, Japan $2.1 billion and the remainder of Europe only $0.5 billion. Compare these numbers to a $5 billion annual tobacco market in the U.S. and the $82.5 billion in pharmacy sales, according to an 1994 analysis by IMS America. The sales represent the slowest growth in 10 years.[1]

The number of people and the level of interest in vitamins and dietary supplements has grown over the past two decades as more and more consensus is achieved on concepts like "free radicals." Complementary and alternative healthcare, or simply the use of more natural remedies, is supposedly gaining daily from a larger pool of believers in individualism and the desire to save a buck in the United States. But it could be that Americans are traveling more and finding plant remedies more available in the other parts of the world. And it could be that some Americans are satisfied in using plant remedies because they work and do not cost very much. In 1993, researchers discovered that 75% of rural Mississippi residents use plant remedies, such as aloe vera, china berry, yellow dock, garlic, American ginseng, Jimson weed, mayapple sassafras and turpentine.[4] Americans are not dunces, they are catching up, and now that the Dietary Supplement and Education Act is being implemented, these sales are likely to increase in a dramatic way. Meanwhile, keep in mind in third world countries, the only medicines available are the plant drugs that their ancestors have used for thousands of years, discoveries by patient observations which later led modern scientists to

> ...it shall be lawful to every person being the King's subject, having knowledge and experience of the nature of Herbs, Roots, and Waters, or of the operation of same, by speculation or practice, of any part ... of the King's dominions, to practise, use and minister in and to any outward sore, uncome, wound, apostemations, outward swelling or disease, any herb or herbs, oyntments, baths, pultes and ampliasters, according to their cunning, experience and knowledge in any of the diseases, sores and maladies beforesaid, and all other like to the same, or drinks for the Stone and Strangury, or Agues, without suit, vexation, trouble, penalty, or loss of their goods.
>
> ---*Statutes of the Realm, 34-35, Henry VIII, c. 8*

confirm usefulness by chemical and pharmacologic methods.

Whether Americans are using plant remedies because they work, because they are affordable for the poor who do not bother with government health programs, or because they are learning about herbal remedies on their foreign trips, pharmacists should begin to ask about these as part of the patient medication history, in order to take them into account in counseling and in designing pharmacy care plans.

FDA says pharmacists are not doing as good a job of consulting with patients about prescription medications as the FDA wants. The "official" FDA thought pattern and public interest theme is, if pharmacists do not do better in consulting about prescription drugs, they will be forced to distribute little folded pieces of paper, which open to the size of a telephone book, to each patient to be sure that everything FDA wants told, will be told.[5]

FDA recently held a meeting in the Washington suburbs to review what it was planning to do to redesign the package insert and make it more useful. Some speakers suggested that FDA require the inclusion of a new section in the professsional labeling to show prescribers what to advise patients about the use of drugs. There seemed to be little opposition to the FDA control of this aspect of labeling. As one speaker put it, many consumers purchase the *Physicians Desk Reference*, so FDA should put the exact wording in the package insert since patients will read these anyway.[6] The publisher of this reference recently claimed its sales of the book was over 101,000 per year. In any case, this number is not close to the number of households in the country, or even the number of physicians and pharmacists who have an interest in professional drug labeling. And, of course, we know that the *PDR* contains only those drugs that companies pay to include.

Given FDA's longterm interest in micromanaging the writing of prescriptions and the use of drugs through the package insert and patient package insert (PPI) proposal of the late 1970s, there is no telling how far the agency will go this time.[7] President Reagan's election in 1980 seemed to cool FDA's ardor for meddling in medicine and pharmacy, but with the present White House, FDA has revived its efforts to move again toward total control of medical and pharmacy speech.

King Henry, the 8th, in the 16th century, often consulted with his Apothecary, Thomas Babham, about techniques of compounding and he make some of his own medicines.[8] The King's statute, quoted at the beginning of this article, uses several words that many pharmacists today probably cannot define. It is important to know that the law was part of a larger effort of Parliament which attempted separation of the activities of physicians, surgeons, barbers and apothecaries and the quoted provisions were intended to make healthcare more readily available to the poor.

The question that obviously arises today, as it did in the 1530's and 1540's, is how do we provide medicine to the poor. If

80 percent of the world's population already uses herbal medicine as its primary medicine; should a pharmacist in an ever more cosmopolitan United States know anything, something or nothing about these medicines?

Given that 20 to 30 percent of today's modern chemical bullet medicine is derived from plants, one might ask how pharmacists can justify not knowing more about herbal medicine. Does it make any sense to urge pharmacists to become more knowledgeable about herbal remedies even if these products are labeled only as "dietary supplements?" It seems to me that it does. It seems to me that pharmacists could be far better prepared to advise on the use of such home remedies than the clerk or investor in a healthfood store who may have little or no scientific education.

Obviously, pharmacists cannot counsel or consult about herbal remedies without preparing as well as they do for modern medicine. Since most practicing pharmacists under 50 years of age neither had a course in pharmacognosy or in late midevil English history, and since the pharmacy curriculum has been overbooked on other areas to fill up the college course of five or six years, pharmacists cannot expect to gain knowledge about herbal remedies without some effort.

Here is a way you can demonstrate to yourself why scientific knowledge of herbal remedies is important. Go to a bookstore and pick up one of several hundred folklore or herbal medicine books.

One such recent book is David Hoffman's *An Elders' Herbal*, Healing Arts Press (1993). In this book you will get an overview of how the master herbalist in the U.S. views the use of herbs in a holistic health practice in which herbs play a role in supplementing and complementing allopathic medicine's drugs and how, in some cases, herbal remedies may be preferable to others. However, Hoffman recommends some ingredients that are suspect in the judgment of others and these require the discerning scientific mind to separate facts from fiction.

For example, Hoffman recommends the use of Comfrey root (*Symphytum officinales*, L.) in remedies for esophagitis, gastroesopheal reflux, gastritis, peptic ulceration, hiatus hernia, ulcerative colitis, as well as in external preparations for musculoskeletal problems in the form of poultices and ointments.

Then go pick up the book titled *Herbs of Choice*, Pharmaceutical Products Press, (1994) by Varo E. Tyler, the Lilly Distinguished Professor of Pharmacognosy at Purdue University, and see what he recommends with regard to the use of Comfrey. After a short review of the active chemical constituents, allantoin and rosmarinic acid, and some discussion of the scientific literature on its use, Tyler makes the following conclusions:

- the internal use of any species of Comfrey should be avoided.
- Comfrey root should never be used medicinally.
- Only the mature leaves of *S. officinale* should be applied externally, and then only to intact skin for limited periods of time.

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- Comfrey should never be used by pregnant or lactating women or by young children.
- Because there are so many non-toxic yet effective treatments for minor skin ailments that do not present the hazards associated with this herb, comfrey has little, if any, place in our modern materia medica.

Tyler's reasons for his recommendations stem from his knowledge that Comfrey root containts a large number of pyrrolizidine alkaloids that are known to cause cancer in young animals. And some Comfrey, he says, contains the extremely dangerous echimidine. He says the roots contain 10 times the PA as do the leaves. In Germany, the PA is limited by standards which require testing of the products. Here in the U.S., the product is not standardized since it is not allowed to be labeled as a drug. And without such labeling in the U.S., pharmacists and others cannot lawfully recommend this herbal remedy for a drug use.

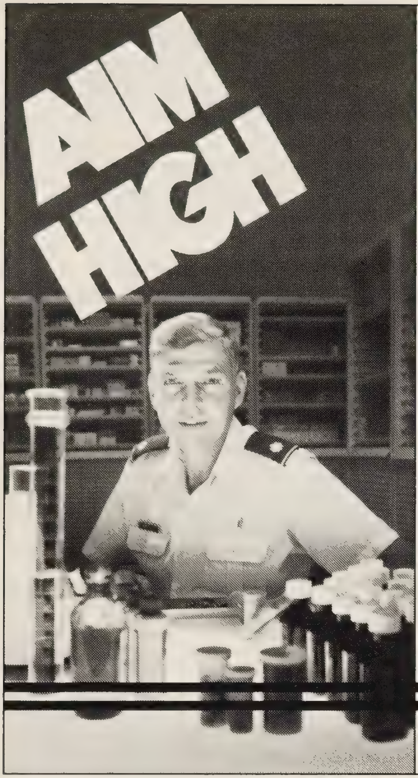
Recently, a more striking comparison between herbal medicine and modern biotech medicine occurred to me. The Schering Corporation has sent me copies of its patient package insert on INTRON®A, Interferon alfa-2b recombinant for injection, as part of a promotion. I read in the clinical pharmacology section that the interferons are a family of naturally occurring small proteins and glycoproteins with molecular weights of approximately 15,000 to 27,000 daltons produced and secreted by cells in response to viral infections. I learned that in 54% of patients responding to this at a dose of 3 million IU for chronic hepatitis Non-A, Non-B/C, 70% achieved reductions of serum alanine aminotransferase (ALT) levels to normal,18% achieved reductions to near normal levels, and 12% achieved a partial response. I do not mean to put down the usefulness of modern biotech medicine. If my physician said I needed it, I would likely use it.

But the real point here is the FDA approved labeling for this product which says it is a naturally occurring compound, made up of several compoents that can only be identified within a range of daltons in weight and whose method of action can only be described as "interferons initiate a complex sequence of intracellular events" the correlation of which to *in vitro* test mechanisms and clinical studies effects is unknown. And the labeling states this product only worked in 54% of patients and in 70% of those (about 38% of the total) was "normal" achieved.

Now compare that to another naturally occurring immunomodulator -- *Echinacea.* Here is a drug that was being used by the American Indians when the pioneers went across the midwest and western U.S. The plant has several species, was once made in several oral forms, and as an injectable, by Lloyd Brothers, Pharmacists, Inc. in Cincinnati. It was the favorite remedy of eclectic doctors who were run out of business by the allopathic medical doctors. However, none of this stopped European phytomedicine scientists from studying this herbal drug, and today, it is one of the most widely used and popluar OTC remedies in Europe. In the U.S., it is available in healthfood stores as a dietary supplement. European physicians have also learned to deal with herbal medicine because their patients use these therapies as a part of family folklore and traditional self-treatment.

In Germany, *E. purpurea* and *E. augustafolia* are approved for use in standardized products as a non-specific stimulant to the immune system to increase the body's own defenses. It is said to increase properdin levels, increase phagocytosis and increase corticosteroids. Oral and injectable forms are sold. Studies have shown that *Echinacea* may work by increasing production of interferon by macrophages. Clinical studies show that it shortens the convulsive stage of whooping cough, shortens bronchitis and tonsillitis in pediatric patients. Dozens of clinical studies have been done in Europe. For a comprehensive review of *Echinacea* you must read Steven Foster's book, *Echinacae: Nature's Immune Enhancer*[9], which contains a history of the plant's use in the U.S. and the world, and citations to clinical studies in Europe.

Comparing interferon with *E. purpurea* is even more striking if you consider the possibilities of the difference in cost of treatment for diseases that might be affected similarly by *Echinacea* as by interferon, regardless of brand or source. That adequate research has not been done on *Echinacea* in the U.S. is almost criminal to my way of thinking, but it is understandable given the cost of compliance with FDA requirements.



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AIR FORCE

As one of the pharmacists who graduated at the end of the four year college program, in which I earned about five years of college credits as a 1960 graduate of Butler University College of Pharmacy, I had a course in pharmacognosy. This course consisted of lectures and laboratories which taught me about plant parts, distillation and extraction of oils, decoctions, seeing microscopically the alkaloids in certain plants, and other information that I imagined, at the time, would be about as useful as knowing the percentage of alcohol in every tincture in the U.S.P and N.F. Of course, we had other courses in "preparations," in which the students learned how-by-doing to make formulas from the *United States Pharmacopeia* and *National Formulary* and to make tinctures, decoctions, infusions, emulsions, and waters. At that time there was not a great deal of emphasis on the pharmacology of these products or on the use of natural products or herbal remedies. Sure, we made Tincture of Digitalis and Rose Water in those days. Henry, the 8th, and I both knew how to make Rose Water, and I suspect he needed it more than I, since the castle baths were not as well supplied with water as they are today for daily hygiene.

Today, herbal remedies are widely used in other parts of the world, as can be confirmed in Max Wichtl's book, *Herbal Drugs*, is now a popular item being purchased by some American pharmacists.[10] Originally published in Germany, and translated to English in the last couple of years, this book is a broad introduction to the whole subject area and it deserves to be on the shelf of any activist pharmacists who consults and compounding pharmacist from now until at least 2020.

There are other good books, too, and there are courses and programs by which a pharmacist can become more knowledgeable of phytomedicine subjects. These sources will be highlighted in Part II of this feature, appearing in the March/April 1996 issue of *The Maryland Pharmacist.*

Does the Law Limit Professional Judgement?

Melvin Rubin, P.D., Secretary and Commissioner
Maryland State Board of Pharmacy

The Board of Pharmacy giveth and the Board taketh away.

It's true that the prime function of the Board of Pharmacy is to protect the health and welfare of the public as it is affected by our profession. The base for that power lies in our duty to license pharmacists who convince us that they are qualified and to revoke that right where we feel it is appropriate.

The Board works within the framework of laws and regulations which call for us to use our judgement to punish those who break those laws. Most of the columns I have written for *The Maryland Pharmacist* over the past year tell you what you cannot or should not do and what might happen if you do. You know, stuff like: don't refill CDS substances more than five times in six months; don't refill a prescription without permission; don't blindly accept the physician's prescription without verifying correct drug and dose; remember that you have a corresponding responsibility specifically related to controlled substances.

It's easy to tell you what you cannot do. Then I hear pharmacists say that they call the Board or other agencies for guidance as to what they *can* do and often are told to use their professional judgement. I can just imagine the pharmacist hanging up the phone and wondering where the law leaves off and allowable judgement takes over when they receive no help from disciplinary agencies or other groups when they ask for advice.

So, after a disclaimer that every case that comes to the Board for potential discipline is handled on its own merits, let me tell you how the current secretary of the Board has handled some problems in his practice. Just don't call and ask if I give you permission to do the same.

Let's take some easy cases first. A patient taking a maintenance drug -- say for hypertension or diabetes -- should not miss a dose even if they did manage to look at a label every day for 100 days that indicated no more refills and not get the message. I have no qualms most of the time about giving enough medication to hold until I reach the prescriber, even if this spans a holiday weekend. Actually, the law allows this with limitations. See Title §12-510 of the Pharmacy Practice Act.

If you don't have a law book, call the MPhA office. It will be a good investment.

Now that the commercial interruption is over, I will admit to occasionally giving a very few pain pills out without authorization when I felt that there was a great and justifiable need. If you think pharmacists can get frustrated by the restrictions of the law, how do you think a cancer patient feels when they run out of medication. This type of judgement has to be followed up by talking to the doctor as soon as possible or sooner. The medication dispensed is always subtracted from the full prescription when obtained.

Use of professional judgement cuts two ways. I recall refusing to refill a nitroglycerin prescription because the patient had been progressively using more and more and would not heed my advice to go to the

doctor or at least be honest with him on the phone. The only way I could get the patient to return to the doctor was to refuse to fill.

Then there was the time I had to refuse to fill pain prescriptions written in apparently good faith by a physician for a patient who had one leg and many other problems. He kept changing doctors and drug stores to satisfy an addiction that probably came from the medication he needed because of all the operations he had had. A pharmacist cannot fill a prescription for a patient to sustain a habit. Once I found that he was playing the field, there was no choice other than to help to cut off his supply in the hope that he would join a program.

A patient that I do not know comes in with a prescription from a physician I also do not know for a narcotic. The address is from the other side of town. How do I know it is a bonafide prescription? Call the doctor and discuss it with him. Of course, the way it usually works is that it is Saturday night and the doctor is not available. The quickest way I have found to determine if it is a good prescription is to offer to give enough to last till Monday. Even if they leave the prescription after getting a few pills, the chances are they will not come back if the prescription was obtained under false pretenses. You may wind up a few pills short in inventory but this use of professional judgement, documented with the prescription, is certainly better than giving out the whole prescription if, indeed, it turns out to be a bad one.

My mother wants more sleeping pills but doesn't want me to call her doctor. Easy call. Sorry Mom, read one of my pharmacy books instead -- they always put me to sleep.

A friend of a friend wants to try the new drug for osteoporosis and gets a doctor friend of the friend to call in a prescription. This is easy, too -- *if* you know all the facts above. I asked the doctor if he was aware of his liability and I let him know that I was going to document the problem. I lost the prescription but kept my professional dignity. If the doctor had said give it anyway, I might have. If it had been, say acetaminophen with codeine, than this scenario would have played out much differently.

It's Saturday evening again and still no doctors available. The patient has only the pharmacist to turn to for help for a (pick one of the following): bee sting, allergy attack, arthritis attack, shortness of breath, sty in the eye, etc. Florida has a law which allows limited pharmacist prescribing accompanied by burdensome paper work. I've been a pharmacist long enough to realize that symptomatic problems can be relieved with OTC drugs in most cases. One of the keys is the confidence of the patient in the advice you give. I don't find it hard to convince a patient that Benadryl 25mg can help as much as any prescription antihistamine.

Pharmacists yearn for a third class of drugs or pharmacist prescribing. Yet, in my practice, I find myself extensively recommending the former prescription only NSAID's, topicals, and nasal and oral decongestants, along with a healthy dose of advice.

How about a patient with chest pain and no history of nitroglycerin on their profile? Tough one. An easy answer is to send the patient to the doctor or emergency room. But let's get them there alive by calming them, having them lie down for awhile, and calling the doctor or 911 instead of just summarily dismissing them as someone you cannot help. Should you give them a nitroglycerin tablet? That might be going to far. I can't define "might" for you.

A patient came in from out of town to visit but forgot his heart medicine and the pharmacy he got the medicine from is closed (Remember -- the toughest problems always come on Saturday evenings). Professional judgement gets tougher and tougher. Each case must be judged on its own merits.

If the patient has no idea what the medicine or strength is, there is just so much you can do. If the patient is well aware of the name and use of the medication, its strength and appearance -- you have some leeway to work with depending on the medication. Just enough to last till Monday even if you make this decision. (Notice how I switch from "I did it" to "you have to decide" when the going gets tough -- this is in writing afterall).

For the past 30 years my practice has been in neighborhood pharmacies where I knew the patients and physicians well. Admittedly, this gave me more confidence to make professional calls than if I worked where there are many transients. Any patient I do not know has to earn *my* confidence to receive extended help. Additionally, being my own boss most of that time, I have not had to worry about management not liking my decisions.

If you work in a pharmacy with a large pass-through population you may have to take more time talking to a patient with a problem in order to fully exercise your judgement and you probably should document every thing you do. Having done that in this era where pharmacist involvement with the patient is used as an advertising tool as much or more than price, I think you might find management more inclined to back up your judgement if push comes to shove. If you want more assurance, ask them their feelings and policies. When you get the expected answer that you have to use your professional judgement, document the conversation. Good pharmacists are in great demand. Good pharmacists help patients. Good pharmacists don't get fired for using good judgement.

As I mentioned at the beginning of this article, the Board judges each case against a pharmacist on its own merits. Our mission is to protect the public. I will go to the mat for a pharmacist who uses good judgement and documentation in helping a patient.

The task force which is reviewing all Maryland pharmacy law is considering the area of professional judgement in its deliberations and I am confident that clearer guidelines will result from their efforts. However, being a professional implies making judgement calls. In today's atmosphere documentation must go hand in hand with any action taken that may be considered by anyone to be an extension of your legal authority. Of course, I will be off the Board in the spring so you might still need a dollar along with my advice to get a large cup of coffee. Just remember, your peers make up the Board and most of them have "been there, too". We have to be tough on pharmacists who abuse their role as keeper of the drugs and on pharmacists who make errors, but the commissioners of the Board of Pharmacy use professional judgement, also.

If you come away from this reading feeling I never did lay out a blueprint for what you should or should not do, you are right. I wouldn't want to take your professional judgement prerogatives away from you. **MP**

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Salicylism

Forgotten, but Not Gone

Cathleen Clancy, M.D., ABMT
Medical Director, Maryland Poison Center

Although the specter of Reye's syndrome has eliminated the use of aspirin in pediatric antipyretic preparations, acute and chronic salicylism remains a major cause of poisoning morbidity and mortality.

Over 27,000 exposures and 35 fatalities (fatality rate, 0.12%) related to salicylates were reported to the American Association of Poison Control Centers in 1994. In the same database, the fatality rate was 0.07% for acetaminophen, and no fatalities related to ibuprofen were reported.

The salicylates commonly encountered as ingredients of pharmaceutical products include aspirin (acetylsalicylic acid), sodium salicylate, salicylic acid (keratolytic), and methyl salicylate. Methyl salicylate (oil of wintergreen), which is often a component of liniments, is the most concentrated of all the salicylate containing products.

Using grains as a measure of acetylsalicylic acid (ASA) adds to the confusion. One grain is equivalent to 65 mg of aspirin (5 grains = 325 mg). There are also enteric coated tablets available which may delay the attainment of peak serum concentrations.

Salicyl-salicylic acid, yields 2 molecules of ASA after metabolism and results in typical salicylate toxicity. Salicylamide, however, is an amide derivative of acetylsalicylic acid and has only mild toxicity, unrelated to salicylism.

Acetylsalicylic acid is a weak acid and is very well absorbed from the acid environment of the stomach and the small bowel. Large doses of aspirin can delay gastric emptying and are poorly soluble in gastric acid; this can lead to bezoar formation. When given therapeutically, peak levels are usually seen within 2 hours, but in overdose the peak may be delayed for 6 or more hours. The small volume of distribution (2.1 L/kg) increases in the presence of acidosis, as the nonionized (uncharged) salicylate molecules cross cell membranes, including those of the blood brain barrier.

One teaspoon of methyl salicylate contains 7,000 mg of salicylate -- equivalent to approximately 21 regular strength aspirin tablets!

Protein binding usually ranges from 50 to 80% but with overdoses, or the presence of hypoalbuminemia, or in the elderly, binding sites are saturated and more drug remains unbound, and this increases toxicity. Once ASA is absorbed, metabolism to the active compound salicylic acid is rapid (20 minutes). Further metabolism to salicyluric acid (75%) and phenolic glucuronide (10%) occurs through pathways that become saturated in overdose. Thus the half-life which is 2 to 4.5 hours at therapeutic dosages, can increase to 20 hours or more in overdose. When the urinary pH is greater than 8.0, most of the unmetabolized drug passing through the tubules is ionized and not reabsorbed; this decreases the half-life to less than 8 hours.

The early clinical manifestations of acute salicylism include hyperventilation, mild confusion, tinnitus and decreased auditory acuity. These mild symptoms can rapidly progress to seizures, coma and death. Usually a progression of clinical signs begin to appear as the salicylate level in the serum and central nervous system increases. These signs include nausea and vomiting, hematemesis, hyperventilation, vertigo, agitation or lethargy, respiratory alkalosis, metabolic acidosis, and refractory seizures.

Although fever is a hallmark of pediatric salicylism, its presence in adults is less frequent and a poor prognostic sign. As the serum salicylate levels rise, noncardiogenic pulmonary edema (rarely seen in pediatric salicylism), refractory seizures, and death are common. Chronic salicylism manifests similar symptoms, although at much lower serum levels, and is often occult. Delays in diagnosis increase mortality.

The metabolic derangements seen with salicylate overdose deserve special mention. Salicylates directly stimulate the medulla and cause hyperventilation and respiratory alkalosis. Concurrent direct effects on intracellular metabolism cause an increased metabolic rate and result in formation of lactate, pyruvate, and other organic acids that, in turn, produce an anion gap metabolic acidosis. The combination of respiratory alkalosis and metabolic acidosis usually produces alkalemia in adults, unless central nervous system depressants were also ingested or the overdose is severe. An overriding metabolic acidosis is more common in children.

Fluid and electrolyte disorders are common including dehydration, hypokalemia, hypocalcemia, and hyperglycemia or hypoglycemia. Overzealous therapy with intravenous bicarbonate can worsen hypokalemia or cause hypernatremia. A paradoxical aciduria is also common as hydrogen ions are excreted in order to retain potassium ions.

The central nervous system is the site of the lethal effects of salicylates. Salicylate levels in cerebrospinal fluid correlate more closely with incidence of death than do serum levels. A critical cerebrospinal fluid salicylate level is achieved over a wide range of serum levels because of equilibration, protein binding and acid base status. In chronic overdoses equilibration has a lesser role, and toxicity is increased.

Enteric coated aspirin can cause delayed onset of symptoms.

Treatment of patients with suspected salicylate overdose includes recognition of the diagnosis, early gastric decontamination followed by multidose activated charcoal, urinary alkalization, monitoring of serial serum salicylate levels (until a decline is confirmed), a close monitoring of fluid and electrolyte balance, and possibly hemodialysis. The effectiveness of urinary alkalinization, without forced diuresis, is based on clear data that shows a marked increase in urinary excretion of salicylate at a urinary pH of 7.5 to 8.0. Although rehydration is important, forced diuresis does not increase the efficacy of urinary alkalinization and is fraught with fluid and electrolyte complications. The Done nomogram, if used properly, is clinically useful only as a very rough guide of severity in acute overdose patients after the peak drug effect.

The Done nomogram was developed to assess and predict clinical severity of acute salicylism, based on a study of 38 acutely poisoned children in 1960. Although the nomogram was based on pediatric data alone, and complex statistic kinetic analysis was not yet available, the nomogram, if used properly, is still clinically useful only as a rough guide of severity in acute overdose patients. Be aware of the proper unit of measure when using the Done nomogram (mg/dL not mg/L or g/L or mmol/L)!

The indications for hemodialysis are primarily clinical. Dialysis should be considered and is often necessary in acutely poisoned patients with a serum level of 100 to 120 mg/dL, or with a deteriorating clinical status (worsening acidosis, decline in mental status, seizures, noncardiogenic pulmonary edema). In chronic overdose, dialysis may be necessary for symptomatic patients with a salicylate level above 60 mg/dL. Patients with renal insufficiency are at particular risk and a low threshold for dialysis should be employed. **MP**

This article from the Maryland Poison Center, located at the University of Maryland School of Pharmacy, was reprinted with permission from the November 1995 issue of Toxalert. References are available upon request. For additional information on the Maryland Poison Center, or for professional assistance, call (410) 706-7604. The Poison Center's Emergency Line, which should be used only for emergencies, is (800) 492-2414.

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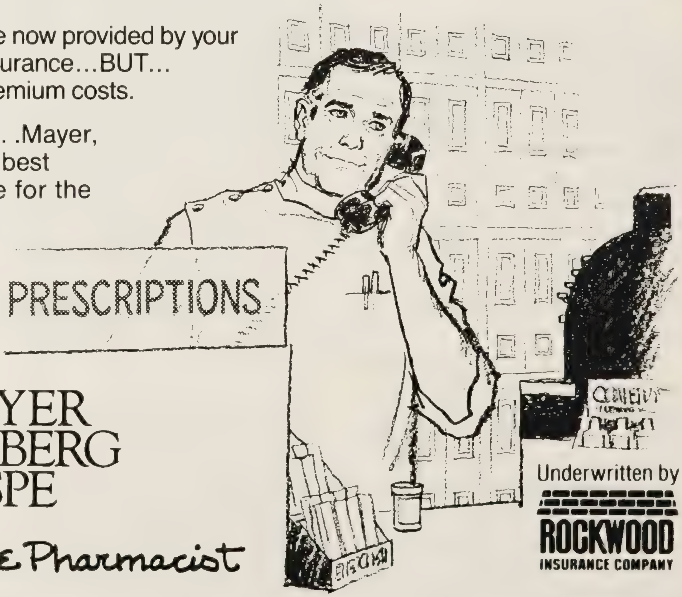

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New Pharmacy Law

Inpatient Institutional Pharmacy Regulations

New Section to the Maryland Pharmacy Practice Act, Subtitle 34, Section 10.34.03

After more than 25 years of work, dozens of iterations, consultations with MPhA and the Maryland Society of Health-System Pharmacists, the Maryland State Board of Pharmacy has promulgated and adopted regulations that govern the practice of pharmacy in inpatient institutional pharmacies. These regulations were considered by the Board of Pharmacy at its public meeting on November 15, 1994, published in *The Maryland Register* of June 9, 1995, and received final approval on October 17, 1995 by the Secretary of the Department of Health and Mental Hygiene. The regulations' effective date is November 6, 1995.

10.34.03 Inpatient Institutional Pharmacy

.01 Scope.

These regulations apply to:

A. A permit-holder that operates a pharmacy that services an inpatient setting; and

B. A person or entity that holds a pharmacy permit and operates a pharmacy in or for an institution other than a long-term care facility.

.02 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Drug" means a medication or other material used in the diagnosis and treatment of injury, illness or disease and which carries a federal legend.

(2) "Emergency drug kit" means a kit containing drugs that are required to meet the emergency needs of patients and which are not available from any other authorized source in a timely manner.

(3) "Institutional facility" or "institution" means any entity other than a nursing home whose primary purpose is to provide a physical environment for patients to obtain inpatient or emergency care, except for urgent care facilities that are not part of an institution.

(4) "Institutional pharmacy" means a pharmacy whether centralized or decentralized, which:

- (a) Provides services to an acute care, rehabilitation, chronic care or mental health hospital;
- (b) Engages in the compounding, sale, or dispensing of drugs;
- (c) May provide nondispensing functions as described in Regulation .17 of this chapter; and
- (d) Has been issued a pharmacy permit pursuant to Health Occupations Article &12-401, Annotated Code of Maryland.

(5) "Medication order" means a patient-specific order that includes:

- (a) Date ordered;
- (b) Drug name;
- (c) Dosage;
- (d) Dosage form;
- (e) Route of administration; and
- (f) Signature of an authorized prescriber, as defined in Health Occupations Article, &12-101(b), Annotated Code of Maryland, or signature of an individual permitted to practice medicine without a license as defined in Health Occupations Article, &14-302, Annotated Code of Maryland.

(6) "Medication protocol" means a course of drug treatment predetermined by the institution and the generally accepted medical practice for proper completion of a particular therapeutic or diagnostic intervention ordered by an authorized prescriber and which, if necessary, allows the pharmacist to infer the existence of certain medication orders.

(7) "Night cabinet" means a locked container located outside of the pharmacy are including cabinets, automated machines, or mechanical devices from which drugs may be obtained pursuant to the standards established by State law.

(8) "Pharmaceutical care" means the direct, responsible provision of medication-related care by the pharmacist for the purpose of achieving definite outcomes that improve a patient's quality of life.

(9) "Type I drug recall" means a drug recall that exists where there is a reasonable possibility that use of or exposure to a violative product will cause either serious adverse effects on health or death.

(10) "Verbal order" means a medication order of an authorized prescriber which is recorded in the patient's chart and countersigned by the prescriber within a time period required by the institution.

(11) Written Order.

- (a) "Written order" means a medication order that is recorded by an authorized prescriber;
- (b) "Written order" includes a transcription of a verbal order from an authorized prescriber which is communicated to the pharmacy in writing, be facsimile copy of the original order, or by electronic transmission.

.03 Issuance of Permits.

The Board shall issue a pharmacy permit to a person or institution before the person or institution established or operated an institutional pharmacy. The Board shall only issue a pharmacy permit to those institutional pharmacies which comply with Health Occupations Article, Title 12, Annotated Code of Maryland, and the regulations promulgated under that title.

.04 Policies and Procedures.

The permit-holder shall provide written policies and procedures which comply with this chapter to the personnel of the pharmacy and, upon request, to an agent of the Board.

.05 Personnel.

A. The permit holder shall appoint a licensed pharmacist as Director of Pharmacy who shall:

(1) Be licensed to engage in the practice of pharmacy in Maryland;

(2) Be in full and actual charge of the pharmacy and its personnel;

(3) Be responsible for the operations of the pharmacy and for compliance with the requirements of Health Occupations Article, Title 12, Annotated Code of Maryland, and the regulations promulgated under that title; and

(4) Review the policies and procedures of the pharmacy annually and revise them as necessary.

B. Staff.

(1) The pharmacy permit holder shall employ a number of additional licensed pharmacists and ancillary personnel as required to competently and safely provide pharmacy services.

(2) The permit holder shall provide written policies and procedures to specify the duties that may be performed by ancillary personnel under the supervision of a licensed pharmacist.

.06 Security.

A. The director shall designate in writing, policies and procedures regarding the personnel that have access to the pharmacy.

B. If a pharmacist is not present, the pharmacist shall lock the pharmacy and any of its decentralized areas before leaving the pharmacy or the decentralized area.

C. The institution shall establish policies and procedures for emergency access to the pharmacy or any of its decentralized areas when locked.

.07 Physical Requirements and Equipment.
A. The institutional pharmacy shall have floor space, shelving, and equipment to ensure that all drugs within the institutional pharmacy are properly stored and prepared with respect to sanitation, temperature, light ventilation, moisture control, segregation, and security.
B. The institutional pharmacy shall have professional and technical equipment, supplies and physical facilities for proper compounding, dispensing, and storage of drugs, including parenteral preparations.
C. The institutional pharmacy shall also have reference materials as required by COMAR 10.34.07.03 to enable personnel to prepare and dispense drugs properly and perform nondispensing functions.
D. The institutional pharmacy shall store alcohol and flammables in areas that meet basic local building code requirements for the storage of volatiles and such other laws, ordinances, or regulations as may apply.

.08 Responsibilities of Director of Pharmacy.
The director or the director's pharmacist designee shall:
A. Be responsible for the safe and efficient dispensing, control, security, and accountability of drugs;
B. Work in cooperation with other professional staff of the institutional facility with respect to the duties listed in this section and in ordering, administering, and controlling drug products and materials, including prescription blanks;
C. Supervise the preparation and sterilization of parenteral and other medications compounded within the institutional facility;
D. Provide written guidelines to hospital staff with regard to admixtures prepared outside the institutional pharmacy including, but not limited to:
  (1) Establishing policies and procedures for preparations and the admixtures, and
  (2) Providing incompatibility information with respect to such admixtures;
E. Recommend specifications for procurement of all drugs, chemicals, and biologicals administered to patients to the appropriate committee of the institutional facility as determined by the governing body;
F. Participate in the development of the formulary when considered appropriate for the facility;
G. Establish procedures for checking the accuracy of labels on all medications dispensed, including, but not limited, to those:
  (1) In vials, syringes, bottles, bags, repacking materials, or bins, and
  (2) In carts, kits, cabinets, refrigerators, biological safety cabinets, laminar flow hoods, or automated machines;
H. Maintain and make available an inventory of antidotes and other emergency drugs, both in the pharmacy and in patient care areas, as well as current antidote information,l telephone numbers of a regional poison control center and other emergency assistance organizations, and such other materials and information as may be considered necessary by the governing body of the institutional facility;
I. Record all transactions of the institutional pharmacy as may be required by applicable law and as may be necessary to maintain accurate control over and accountability for all pharmaceuticals;
J. Offer to participate in those aspects of the institutional facility's quality assurance and improvement program, which relate to pharmaceutical utilization and effectiveness;
K. Offer to participate in teaching or research programs, or both, in the institutional facility;
L. Implement the policies and decisions of the governing body of the institutional facility related to these regulations; cure, and efficient messenger and delivery services for pharmaceutical products within the facility;
M. Ensure that a system is in place that provides safe, secure, and efficient messenger and delivery service for pharmaceutical products within the facility;
N. Ensure that the institutional pharmacy meets all inspection and other requirements of Health Occupations Article, Title 12, Annotated Code of Maryland, and these regulations;
O. Develop and implement policies and procedures to insure that discontinued and out-dated drugs and drug containers with worn, illegible, or missing labels are returned to the pharmacy for proper disposition;
P. Establish policies and procedures for identification, handling, and disposal of medications brought into the institution by the patients;
Q. Conduct an on-going plan for a quality management program that will review and evaluate pharmaceutical services and recommend improvements in these services;
R. Establish policies and procedure for identification and handling of investigational drugs that include the provision of pharmacologic and toxicologic information to the medical and nursing staff as soon as possible and not longer than 48

hours after the administration of an investigational drug; and

S. Arrange for the evaluation of all drug storage areas throughout the institution on a monthly basis and maintain written record of these reviews.

.09 Drug Dispensing -- Record Keeping.

A. The director or the director's pharmacist designee shall establish and maintain a master log for all drugs that are repackaged from bulk packages before the receipt of a medication order for internal, external, or injectable use within the institutional facility which lists the following information:

(1) Name of Drug;
(2) Strength;
(3) Manufacturer;
(4) Lot Number;
(5) Quantity repackaged;
(6) Expiration date of repackaged drugs;
(7) Manufacturer's expiration date;
(8) Date of repackaging;
(9) Name of repacker; and
(10) Name of verifying pharmacist.

B. The director or the director's pharmacist designee shall determine whether generic products are properly labeled, including the name of the manufacturer of these generic products.

C. Section A of this regulation does not apply to any injectables dispensed within 72 hours of repackaging.

.10 Labeling for Use Outside the Institutional Facility.

A. The director or the director's pharmacist designee shall ensure that the labels on all drugs dispensed for use outside the facility by an institutional pharmacy to clinic, ambulatory patients, or other patients about to be discharged meet the requirements of Health Occupations Article, &12-509, Annotated Code of Maryland.

B. The director of the director's pharmacist designee shall ensure that the label contains any other information that may be required by federal or State law or regulations including, but not limited to, cautionary information.

.11 Drug Dispensing -- Emergency Supplies and Procedures.

A. The director shall offer to assist the medical staff in determining which drugs and what quantity of those drugs should be included in emergency drug kits maintained by the institutional permit holder.

B. The director or the director's pharmacist designee shall, in conjunction with the medical staff of the institutional facility, develop and implement written policies and procedures to ensure compliance with the provisions of this regulation.

C. The director or the director's designee shall furnish emergency drug kits only if:

(1) The emergency drug kits are stored in an environment permitting the preservation of the drugs inside and providing accessibility only to authorized personnel;
(2) The institution follows a policy that drugs will be dispensed form the emergency drug kit only upon written or verbal order by an authorized prescriber or by a pharmacist;
(3) The emergency drug kits are stocked and maintained in a manner that complies with the standards of applicable State law;
(4) The emergency drug kits are secured with a tamper evident seal and kept in a secure area;
(5) The emergency drug kits are labeled as follows:
    (a) Clearly indicating that it is an emergency drug kit and that it is for use in emergencies only,
    (b) Listing the expiration date of the emergency drug kit, and
    (c) Listing the name or initials of the pharmacist who checked the emergency drug kit;
(6) When the emergency drug kit is contained within a cart, the pharmacist checking the cart shall ensure that the exterior of the cart is labeled with the contents of the kit and the name or initials of the pharmacist; and
(7) The director or the director's pharmacist designee shall ensure that all repackaged drugs contained in emergency drug kits are labeled in accordance with Regulation .09 of this chapter, and are also labeled with such other information and may be required by the medical staff.

D. Upon notification that an emergency kit has been opened, a pharmacist or pharmacist's designee shall restock the kit as soon as possible or provide another kit.

E. The director or the director's pharmacist designee shall ensure that the expiration date of an emergency drug it is the earliest date of expiration of any drug supplied in the emergency drug kit. Upon occurrence of the expiration date, the pharmacist or the pharmacist's designee shall replace the expired drug and relabel the kit as provided in &C(5) of this regulation.

.12 Drug Dispensing -- Prescribers' Orders.

A. Drugs may be dispensed form the institutional pharmacy only in response to medication orders issued by prescribers who have been authorized to do so by law and by the governing body of the institution.

B. Documentation.

- (1) Medication Protocols.
  - (a) The pharmacist may dispense, or make available, drugs for medication protocols if conditions designated by the institution are met.
  - (b) The director or the director's pharmacist designee shall assist in establishing institutional policies and procedures governing each individual situation for which medication orders are implied due to a therapeutic or diagnostic intervention. The appropriate committee of the institution shall endorse the institute the policies and procedures before the pharmacist may fill the implied orders.
- (2) A pharmacist shall fill orders including abbreviations and chemical symbols only if the abbreviations and symbols appear on a published list of accepted abbreviations developed by the appropriate committee of the institutional facility.
- (3) The director or the director's designee shall keep available patient information necessary for drug monitoring including the patient's:
  - (a) Sex;
  - (b) Age;
  - (c) Weight;
  - (d) Height;
  - (e) Diagnosis; and
  - (f) Allergies.

.13 Controlled Dangerous Substances.

A. Drug Accountability.

- (1) The director shall be responsible for the establishment of effective procedures and the maintenance of adequate records regarding use and accountability of Schedule II controlled dangerous substances which specify at least the following:
  - (a) Name and strength of drug;
  - (b) Dose;
  - (c) Dosage form;
  - (d) Prescriber;
  - (e) Patient;
  - (f) Date and time of administration; and
  - (g) Individual administering the drug;
- (2) The director shall be responsible for the establishment and maintenance of adequate records of delivery and receipt into inventory of all controlled dangerous substances, which specify the signature of the individual:
  - (a) Delivering within the institution; and
  - (b) Receiving the controlled dangerous substance.
- (3) The director or the director's pharmacist designee shall be responsible for the establishment and maintenance of adequate records of partially administered Schedule II controlled dangerous substances for disposal or return of unused drugs to the pharmacy. The director or the director's pharmacist designee shall specify that these records include the signature of the individual authorized;
  - (a) By the institution to dispose of drugs or to return them to the pharmacy; and
  - (b) To witness the disposal, as defined by the institution's policy and procedures.

B. Storage and Security. The institutional pharmacy permit holder may not dispense Schedule II controlled dangerous substances unless the following security precautions exist in the institution and the pharmacy:

- (1) Access to controlled dangerous substances outside the pharmacy is restricted to licensed personnel approved by institutional policy;
- (2) Controlled dangerous substances stored outside the pharmacy are accounted for at least at the change of each shift by licensed personnel authorized by the institution, unless a controlled access automated dispensing system provides an on-demand report of a perpetual inventory;
- (3) On at least a monthly basis, a pharmacist or an individual designated by the director shall perform a physical count of each Schedule II controlled dangerous substance in the pharmacy and shall then compare that count with the perpetual inventory maintained by the pharmacy

with reference to the particular drug;
(4) On at least a monthly basis, the director or the director's pharmacist designee investigates discrepancies, reports losses as required by law, and takes appropriate action; and
(5) The director or the director's pharmacist designee establishes a procedure by which previously dispensed Schedule II controlled dangerous substances that are no longer necessary for medical reasons are returned to the pharmacy.

.14 Type I Drug Recalls.

A. The director or director's designee shall develop and implement a Type I drug recall procedure that can be readily activated to assure that all drugs which have been recalled are returned to the pharmacy for proper disposition.

B. If a drug has been recalled under a Type I drug recall, the director or director's designee shall issue a notice to inform all affected departments of the institution that the drug should be returned to the pharmacy.

.15 Adverse Drug Reactions.

A. The director or the director's pharmacist designee shall offer to participate in the appropriate committee or committees to establish procedures to report and record adverse drug reactions;

B. The director or the director's pharmacist designee shall immediately report adverse drug reactions detected by the pharmacist to the attending prescriber, or the prescriber's designee, and make a written report in the patient's chart, if allowed, and report the reaction to the appropriate committee or committees, as determined by the governing body of the institutional facility; and

C. The director or the director's pharmacist designee shall make further reports of such adverse reactions to the U.S. Food and Drug Administration, or other regulatory bodies as required by federal or State law.

.16 Drug Dispensing Records and Reports.

The director shall maintain such records and reports as may be required by federal and State laws and these regulations, including, but not limited to, a master log of repackaged drugs as described in Regulation .09 of this chapter.

.17 Nondispensing Functions of the Pharmacist.

A. The pharmacist shall be available to provide pharmaceutical care to individual patients including, but not limited to:
(1) Education and counseling;
(2) Prevention, detection, and resolution of drug-related problems; and
(3) Initiation and modification of drug orders.

B. The pharmacist shall be available to provide other nondispensing functions, including;
(1) Drug and poison information, consistent with scope of practice;
(2) Drug utilization review and drug use evaluation; and
(3) Education of pharmacy employees and other health care providers.

.18 Administration of Drugs.

A. The director or the director's pharmacist designee practicing in a setting covered by this chapter shall participate in developing and monitoring the policies and procedures pertaining to the:
(1) Administration of drugs at an institutional facility to ensure that only authorized individuals administer drugs; and
(2) Self-administration of drugs by patients to ensure that the administration occurs in accordance with procedures established by the appropriate committee of the institution and that the self-administration is ordered by an authorized prescriber.

B. The director or the director's pharmacist designee shall ensure that significant medication errors and significant adverse drug reactions are reported in a timely manner, in accordance with written procedures.

C. The pharmacy department/service, in collaboration with the medical staff and other appropriate departments/services, shall develop and maintain a process for defining, identifying, and reviewing significant medication errors to determine causes of errors and develop actions to prevent reoccurrences; and

D. The pharmacy department/service, in collaboration with the medical staff and other appropriate departments/services, shall develop and maintain a process for defining, identifying, and reviewing significant adverse drug reactions to determine causes of adverse drug reactions and develop actions to prevent reoccurrences. **MP**

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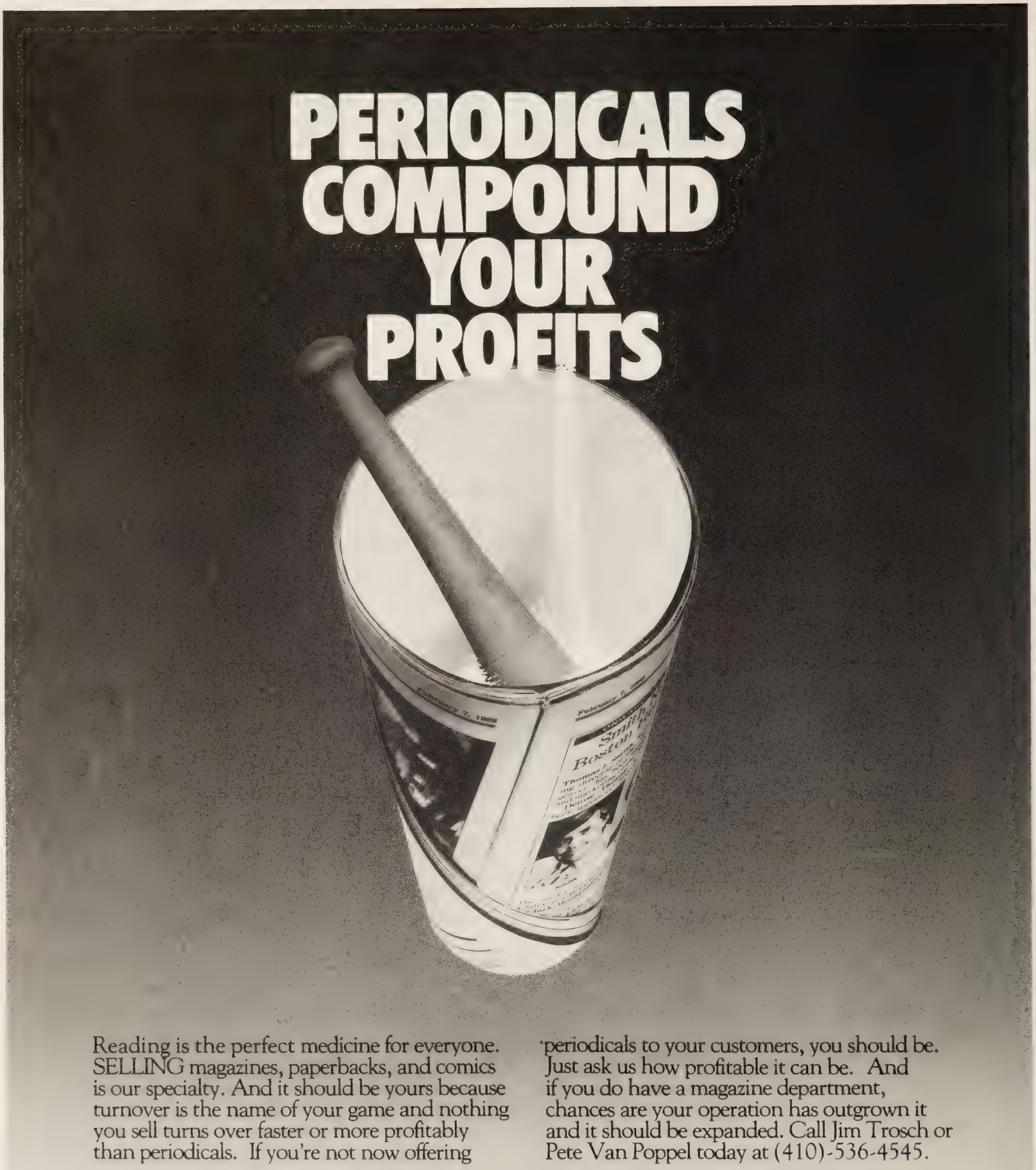

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Litigation Update

Conscious Disregard

Every pharmacist knows that certain prescribers are only supposed to issue prescriptions for diseases or conditions that are within their scope of practice. But many are uncertain what the implications of failing to enforce that policy.

The Supreme Court of Alabama has issued an interesting recent opinion clarifying its earlier opinion in a case I reviewed last month in this column. The new opinion is a substitute for the earlier opinion while at the same time affirming the earlier decision. The previous court opinion upheld an award of punitive damages against a pharmacy based on a finding of "wantonness." Such an award can be supported only if a pharmacist has engaged in conduct that is carried on with a reckless or conscious disregard of the rights or safety of the patient.

The key questions in the case were the failure to note that a prescription does not correspond well with the specialty of the prescriber, and the failure to use knowledge of past misfillings to institute a program to prevent future misfillings (institutional controls).

David B. Brushwood, R.Ph., J.D.

The court said, "We believe that a prescription from an oncologist that a pharmacist believes to call for a heart medication used by cardiologists to treat arrhythmias or serious heart ailments, should cause her grave concern and necessarily prompt further inquiry. The extreme unusualness of a prescription from a cancer specialist supposedly calling for a dangerous heart medication, combined with the alleged illegibility of the prescription, is sufficient evidence of a reckless disregard of the safety of others to create a jury question as to whether [the pharmacy's] actions under those circumstances rose to the level of a conscious or reckless disregard for the safety of [the patient]."

The court also ruled that the pharmacy company's incident reports, complaints to the state board of pharmacy, and prior lawsuits filed against the company were relevant to show the company's knowledge of problems within its pharmacies, and thus were admissible to support the wantonness claim predicated on the company's having failed to initiate sufficient institutional controls over the manner in which prescriptions were filled.

This second opinion serves as a huge exclamation point following a careful review by the court of the facts and law of pharmacist malpractice. Pharmacists must carefully review prescription they receive to assure to promote accurate dispensing! **MP**

Based On: Harco Drugs, Inc. v. Holloway, 1995 Ala. LEXIS 418 (October 27, 1995). Copyright 1995, David B. Brushwood. All Rights Reserved. Reprinted from *Dickinson's Pharmacy*, November, 1995.

Continuing Education

New Drug Review
Losartan and Moexipril

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A professional development program made possible by an educational grant from **SEARLE.**

It is estimated that more than 43 million Americans have hypertension with fewer than one-half of them receiving any treatment. Prolonged high blood pressure is associated with a 200 to 400 percent increase in the development of cardiovascular problems including heart attack, heart failure, strokes, angina, peripheral vascular disease and kidney failure.

In spite of efforts to convince hypertensive patients to comply with their drug therapy, studies continue to show a high rate of drop out and noncompliance. One such study reportedly found that nearly 40 percent of patients receiving first-line antihypertensives (thiazides, beta-blockers, calcium channel blockers and angiotensin converting enzyme inhibitors) discontinue their medication within 3 months of beginning therapy. Seventy percent of patients placed on antihypertensive drugs discontinue their medication after one year.

These are amazing statistics but they must be tempered downward because the study was a blinded review of pharmacy records. Therefore it cannot be determined whether what appeared to be stopping therapy was actually due to patients switching to another pharmacy for refills, having their therapy changed to a different antihypertensive drug or dosage, or whether the physician wrote a new prescription rather than authorizing refills for previous medications.

Nonetheless, it is known that compliance is a problem with antihypertensives therapy and the search for more effective drugs with greater patient acceptance continues. One of the difficulties in treating hypertension is that the disease has no perceptible symptoms that can be "felt" by the patient. Certainly high blood pressure can be measured by the use of a sphygmomanometer, but the patient cannot feel the blood vessels constricting.

Also, antihypertensive drugs invariably cause annoying side effects. Therefore, it is difficult to make a person feel better when he or she doesn't feel bad in the first place, especially when the patient will receive medications that invariably cause side effects.

The ideal antihypertensive drug would be "user friendly"' that is, bring about a smooth lowering of blood pressure compared to the more immediate and profound action of some of the other agents, and have a once-daily dosing schedule and a low incidence of side effects. Losartan is touted as having all three of these attributes.

The Renin-Angiotensin-Aldosterone System

One of the key components of the mechanism for maintaining hemostasis and controlling ideal blood volume throughout the vasculature and the tissues of the body is the renin-angiotensin-aldosterone (RAA) system. This system is an important factor in the pathophysiology of hypertension.

Renin is the primary enzyme responsible for the metabolism of angiotensinogen, the inactive precursor to angiotensin I, which in turn is the precursor to angiotensin II. Aldosterone is a mineralocorticoid produced in the adrenal cortex which is responsible for the exchange of potassium and hydrogen ions to reabsorb sodium in the distal tubules of the kidneys.

The RAA system is involved in many other hemostatic processes including the vasomotor center in the brain which is responsible for maintaining vasomotor tone in the arteries. To quickly review, when a bolus of blood is pumped out of the heart, there is insufficient pressure to send it through the miles of vessels in the cardiovascular system, and against gravity as it makes its way back to the heart from the lower extremities.

Therefore, the arteries must be slightly constricted at all times. They are comprised of elastic tissue, able to dilate and constrict. When the bolus of blood leaves the heart, it exerts physical force on the arterial walls causing them to dilate. As the blood travels through a given area of blood vessels, vasomotor tone induces them to return to their previous, constricted mode. This forces the blood along the cardiovascular system and back to the heart.

The transformation of angiotensin I to angiotensin II is catalyzed by the enzyme angiotensin converting enzyme (ACE). The angiotensin II formed by this metabolic action is the most potent vasoconstrictor produced in the body. It also stimulates the adrenal gland to secrete aldosterone. Another primary activity of angiotensin converting enzyme is the conversion of bradykinin, a potent vasodilator, to its inactive metabolites.

Drugs Affecting the
Renin-Angiotensin-Aldosterone System

Generic	Trade	Availability	Dosage Regimen
Angiotensin II Blocker			
Losartan	Cozaar	25 & 50mg tablets	50mg daily
Losartan/HCTZ	Hyzaar	50mg losartan/12.5mg hydrochlorothiazide	1 tablet daily
New Angiotensin Converting Enzyme Inhibitor			
Moexipril	Univasc	7.5 & 15mg	7.5mg daily, 1 hour before meals
Previously Available Angiotensin Converting Enzyme Inhibitors			
Benazepril	Losentin	5, 10, 20, & 40mg	20-40mg QD or BID
Captopril	Capoten	12.5, 25, 50, & 100mg	25-150mg BID or TID
Enalapril	Vasotec	2.5, 5, 10, & 20mg	10-40mg QD or BID
Fosinopril	Monopril	10 & 20mg	20-40mg QD or BID
Lisinopril	Prinivil	2.5, 5, 10, 20 & 40mg	20-40mg QD
	Zestril	5, 10, 20, & 40mg	
Quinapril	Accupril	5, 10, 20 & 40mg	20-80mg QD or BID
Ramipril	Altace	1.25, 2.5, 5 & 10mg	2.5-20mg QD or BID

Perindopril [Aceon] and Spirapril [Renormax] had been approved but were not marketed at the time this lesson was written.

Table One

When the RAA system functions properly, there is a balance of sodium and water reabsorption from the kidneys to increase blood volume, as well as vasoconstriction and vasodilation to properly maintain hemostasis. All areas of the body are supplied with adequate blood flow most of the time, more when needed and less when other areas require increased amounts.

The amount of angiotensin II that is formed, and the resultant secretion of aldosterone are considered to be important in the pathogenesis of hypertension. The ACE inhibitors (Table One) have been used extensively in the treatment of mild to moderate hypertension. The ACE inhibitors are first-line therapy along with the diuretics, ß and calcium channel antagonists.

Losartan

Losartan {low-Czar-tan/Cozaar} has a relatively long duration of action allowing it to be administered on a once-daily basis. This is because after absorption, losartan is metabolized in the liver by cytochrome P450 (mixed oxidase) enzymes to its carboxylic acid metabolite.

Although losartan is active, this metabolite is reported to be 40 times as potent. Losartan, itself, has a half-life of only 1.5 to 2.5 hours, but its active metabolite has a half-life of six to nine hours, providing the once-daily dosing efficacy.

The role of the increased duration of action of this metabolite has been demonstrated in dogs and rhesus monkeys where losartan is only minimally metabolized to the carboxylic acid moiety. In these animals, losartan lowered blood pressure but had a considerably shorter duration of action.

Taking losartan with a meal slows its absorption and lowers its maximal serum concentration, but does not significantly affect the overall biological half-life of the drug or its metabolite. Therefore, the tablets can be taken with meals or on an empty stomach. The general rule is to always take the dose with meals, or always on an empty stomach to maximize consistent absorption.

Boxed Warning for Cozaar and the ACE Inhibitors

Use in Pregnancy
When used in pregnancy during the second and third trimester, drugs that act directly on the renin-angiotensin system can cause injury and even death to the developing fetus. When pregnancy is detected Cozaar {or any ACE inhibitor} should be discontinued as soon as possible. See WARNINGS: Fetal/Neonatal Morbidity and Mortality

Editor's Note: The warning information is presented in the text of this article under Side Effects.

Table Two

Only small amounts of losartan and its primary carboxylic acid metabolite are excreted in the urine. This suggests that they are further metabolized into inactive chemicals.

Unlike the ACE inhibitors which interfere with the synthesis of angiotensin II, losartan blocks angiotensin at its physiologic receptor sites. ACE inhibitors reduce the formation of angiotensin II via a mechanism involving angiotensin converting enzyme. However, angiotensin II is also formed by other enzymes that are not blocked by ACE inhibitors.

By blocking the binding of angiotensin II to its type 1 (AT-1) receptors in vascular smooth muscle and the adrenal gland, losartan and its active metabolite inhibit the RAA system more completely and more selectively than the ACE inhibitors. This gives the drug the potential to provide more efficient blockade of the cardiovascular actions of angiotensin II while causing fewer side effects.

Neither losartan nor ACE inhibitors affect the hormonal or ion channel components involved in blood pressure regulation. The outcome of this is that losartan can provide increased therapeutic benefit with a higher level of patient compliance.

These differences in pharmacologic action also provide the potential for concurrent use of losartan and an ACE inhibitor in patients who do not respond to either agent alone. Manufacturers may not make this claim, but physicians have the right to initiate concurrent therapy if they feel the patient will benefit. By interfering with the breakdown of bradykinin, a substance involved in the metabolism of prostaglandins, ACE inhibitors alter the levels of prostaglandins in the area of their activity. In the lungs, this leads to coughing. Losartan does not exert an effect on bradykinin.

Similar to the ACE inhibitors, losartan has not been reported to change the heart rate. This is an advantage over some other antihypertensives since it lowers the blood pressure without causing reflex tachycardia. While not an approved indication for losartan, more and more of the ACE inhibitors are gaining approval for use in treating congestive heart failure (captopril, enalapril, lisinopril, quinapril) and diabetic neuropathy (captopril). Time will tell whether losartan will be useful for these indications.

Because it is metabolized by the cytochrome P450 enzyme system, a group of mixed-oxidase enzymes that has received a lot of notoriety in the arena of drug interactions, one may surmise that losartan could be involved in the interactions caused by drugs that inhibit or induce this system (e.g., cimetidine, erythromycin, ketoconazole).

Some studies have been performed to determine the potential significance of this. Concurrent administration of cimetidine, one of the classic cytochrome P450 enzyme inhibitors, resulted in increased serum levels of losartan but had no effect on its active metabolite. Therefore, this is not considered to be a significant interaction. Losartan may be metabolized more slowly, but the differences in half-lives between losartan and its primary metabolite reduce the potential for a significant change in duration of action or potency.

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Ketoconazole, troleandomycin (a member of the macrolide family of antibiotics with erythromycin) and sulfaphenazole (a sulfonamide not available in the U.S.) have been studied *in vitro* (i.e., in test tubes but not in humans) and have shown significant inhibition of losartan to its active metabolite. The clinical significance of this is not known, but there are alternative therapies to all of these agents that may be safer.

Concurrent administration of losartan with warfarin, digoxin and hydrochlorothiazide did not affect the pharmacokinetics of any of these drugs or losartan.

In spite of its action on renal potassium secretion, losartan has very little effect on serum potassium levels. This is surprising since ACE inhibitors increase serum potassium levels and are contraindicated with potassium sparing diuretics and potassium supplements. Therefore, the potassium-sparing diuretics should only be used with a great deal of caution and patients should be advised to avoid OTC salt substitutes until first checking with their physician.

Since the drug is newly released, one must look to clinical trials for information on potential side effects. Except for a low incidence of dizziness, losartan has not shown side effects greater than those seen with the placebo. However, clinical trials do not relate entirely to the general population and there were no high risk patients or those with impaired renal function or multiple disease states.

Of the 4,058 patients in clinical trials, 2.3 percent receiving the drug dropped out due to adverse effects. In the placebo group, 3.7 percent dropped out because of perceived side effects. Therefore, the drug looks to relatively safe, but time will tell how it stacks up against the ACE inhibitors.

A Template for Tomorrow

The 1996 MPhA Mid-Year Educational Seminar

Sunday, February 25, 1996
Loews Annapolis Hotel, Annapolis, Maryland

About this Event

The MPhA Mid-Year Meeting is the *must* attend gathering of pharmacists! It's an opportunity to learn from and network with other pharmacists in a relaxed and enjoyable environment. This year's program includes a review of new drugs and therapies as well as special presentations on the future of healthcare and pharmacy.

Registration

Advance registration for this six credit program is $50 for MPhA members ($60 for non-members). To register, complete the registration form at the bottom of this brochure and return it to MPhA. Questions? Call us at (800) 833-7587.

Learning Objectives

At the conclusion of this program, the attendee will be able to:

- Recount the historical forces affecting America's healthcare system and how which forces will continue to affect the future of that system.
- List five changes in prescription benefit management that will affect delivery of pharmaceutical care.
- Describe the pharmacology and therapeutics of new drug entities released in 1995.
- Describe the therapeutic use of new drug entities in community and institutional practice settings.

Program

8:00 am	Registration and Continental Breakfast
8:30 to 9:30 am	**The Template for Tomorrow's Health Care System** Carl Schramm, Past President Health Insurance Association of America
9:30 to 10:30 am	**The Template for Tomorrow's Prescription Benefit Programs** Louis Sesti, R.Ph. Vice President, PCS Health Systems
10:30 to 11:30 am	Presentations by Board of Pharmacy Candidates
11:30 to 12:30 pm	**New Drugs and Therapies** Robert A. Kerr, Pharm.D. David S. Roffman, Pharm.D. University of Maryland School of Pharmacy
12:30 to 1:30 pm	Buffet Luncheon
1:30 to 4:30 pm	**New Drugs and Therapies** ***Continued***

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Two side effects that have *not* been reported are the annoying cough that is bothersome to many patients taking ACE inhibitors and angioedema, a rare but painful condition caused by localized vasodilation under the upper layers of the skin. Both of these side effects, induced by ACE inhibitors, are linked to their inhibition of bradykinin and substance P metabolism.

With cough, the cause is related to increased formation of prostaglandins (due to higher levels of bradykinin) and substance P in the lungs, leading to irritation and cough. With angioedema, the vasodilation induced by bradykinin (excessively because it is not being metabolized at the proper rate) causes pressure and pain in the affected area and physical changes in the upper layers of the skin.

Because losartan selectively inhibits angiotensin II from binding to its receptors and has no action on ACE, bradykinin and substance P metabolism is not reduced. Therefore, lung tissue is not irritated and subdermal vasodilation does not occur. With cough, 3.4 percent of treated patients reported cough compared to 3.3 percent of those receiving the placebo. This difference is not considered to be clinically significant.

There was only one adverse effect reported for losartan above the five percent level during its clinical trials. Upper respiratory infection was reported at the 7.9 percent level as compared to 6.9 percent for the placebo. This was not considered to be due to the drug, however. Other adverse effects reported for losartan were dizziness 3.5 percent (versus 2.1 percent for the placebo); cough 3.4 percent (versus 3.3 percent); diarrhea 2.4 percent (versus 2.1 percent); and nasal congestion 2.0 (versus 1.2 percent).

Losartan labeling is required to contain the same boxed warning as the ACE inhibitors (Table Two). These later drugs have been reported to cause fetal and neonatal morbidity and death when administered to pregnant women. It has been determined that drugs which act directly on the RAA system during the second and third trimester can cause hypotension, neonatal skull hypoplasia, hypoplastic lung development, fetal limb contractures, craniofacial deformation, anuria, renal failure and death. While these adverse effects have not been proven to have occurred with losartan, its similarity of action on the RAA system necessitates the need to discontinue the drug in women who become pregnant. This pregnancy warning is different than most other drugs which are dangerous during the first trimester when fetal cells are differentiating and the drugs cause teratogenic effects.

Drugs that affect the RAA system have not been shown to cause birth defects during the first trimester so the warning statement to avoid pregnancy is not needed. However, women who are exposed to losartan during this early period of pregnancy should be warned of the potential problem.

It is not known whether losartan is excreted in breast milk, but it has occurred in rats. Because of the possibility that it may be excreted and cause adverse effects in the nursing infant, the benefit to the breast-feeding mother versus risk to her infant decision needs to be made before using the drug.

The dosage for losartan is 50mg once daily, with a range of 25 to 100mg once or twice a day for most patients. Higher doses have not provided additional benefits and lower doses have generally been less effective. This statement refers to most patients. There are sub-populations of patients such as those with impaired liver function and volume depleted patients for whom the recommended starting dose is 25mg. Occasionally patients may need more than 50mg, but the upper limit is 100mg.

Losartan is manufactured by DuPont, who original developed the drug. Merck received marketing rights to the drug in exchange for Sinemet shortly after the DuPont Merck company was formed in the 1980s, and took over the research and clinical trials to bring it to the market.

Additional information useful in counseling patients and caregivers is listed in Table Three.

Patient Counseling Tips for Cozaar

* Cozaar is used to lower blood pressure in hypertensive patients.
* Cozaar may be taken without regards to meals. If it upsets your stomach, take it with food. It is best to either always take the dose on an empty stomach or with food. Cozaar should be taken at approximately the same time every day.
* It is important that Cozaar be taken exactly as prescribed to maximize its effects.
* Some patients have experienced lightheadedness while taking Cozaar. If this occurs, sit or lie down at the first signs. Avoid sudden changes in posture. Be careful going up and down stairs. Be careful driving or performing hazardous tasks.
* Do not take nonprescription cough/cold, asthma, or diet medications and do not use salt substitutes without asking your doctor or pharmacist. They may aggravate your condition or interact with Cozaar.
* Women: If you become pregnant, consult with your doctor promptly about switching to a different drug.
* There are few side effects reported with Cozaar. However, inform your doctor if you experience diarrhea, dizziness, muscle pain, cough, or any other bothersome or unusual side effect.

Table Three

Hyzaar

Hyzaar {HI-czar} is a combination of losartan and hydrochlorothiazide which reduces blood pressure to greater extent than losartan alone. The mean systolic/diastolic reduction in blood pressure brought on by losartan was 7.5/6.8 mmHg. The addition of a low dose of hydrochlorothiazide (12.5mg) to losartan 50mg resulted in a significant further reduction in the diastolic blood pressure in patients in clinical trials.

The discontinuance rate for the combination was 2.8 percent versus 2.3 percent for the placebo. The starting dose is one tablet daily. More than two tablets daily is not recommended. The combination is not indicated for initial therapy. It is appropriate after the patient fails to respond to either drug alone. The manufacturer has chosen to price Hyzaar the same as Cozaar so there is no increase in cost when the patient is transferred to the combination.

Moexipril

Moexipril {mow-ex-a-PRIL -- Univasc} is an ACE inhibitor with the same mechanism of action as other members in its pharmacologic classification (Table 1), explained earlier in this lesson. It is available in 7.5 and 15mg tablets with a dosage regimen of 7.5 to 30mg daily in one or two divided doses one hour before meals for most patients. Those with impaired renal function should be started at 3.75mg once daily. They can be titrated upward to a maximum of 15mg daily.

The drug is indicated for the treatment of hypertension alone or in combination with thiazide diuretics. As with losartan, time will tell whether it will also be approved for treating congestive heart failure.

As with any ACE inhibitor, patients should report signs or symptoms of angioedema to their physician immediately. These include swelling of the face, eyes, lips, tongue, mucous membranes in the mouth, larynx, or extremities; difficulty in swallowing or breathing; and hoarseness. The drug should be discontinued until they receive instructions from their physician.

Patients should be warned of the possibility of lightheadedness or fainting spells (signs of hypotension) especially during the first days of therapy. These should be reported to their physician. Inadequate fluid intake or excessive sweating, vomiting and diarrhea can increase the potential for hypotension.

Similar to the other ACE inhibitors, patients taking Univasc should not use OTC salt substitutes. They contain potassium chloride and can lead to hyperkalemia since ACE inhibitors reduce potassium exchange in the renal tubules via their action on aldosterone secretion. Sympathomimetics can aggravate hypertension due to their vasoconstrictive activity. Therefore, patients taking ACE inhibitors should check with their physician or pharmacist before self-medicating with OTC decongestants, weight control products and antiasthmatic agents.

Being the tenth ACE inhibitor to be approved in the U.S., moexipril's manufacturer may have difficulty making inroads into already established markets for these earlier available drugs. The initial marketing plan is to price the product substantially below the other ACE inhibitors.**MP**

UMAB's Nontraditional Pharm.D. Pathway

R. Gary Hollenbeck, Associate Dean
University of Maryland School of Pharmacy

In the October issue of the journal, MPhA member Lance Berkowitz provided "Another Perspective on the Pharm.D. Degree." As I read the editorial, I recalled the story of the three blind men describing an elephant; each accurately describing a part of the elephant, but none providing an accurate picture of the whole. Some may agree that pharmacists may not ever be able to manage patients' total pharmaceutical care as a part of a health care team. However, no one can deny that the delivery of pharmaceutical care is occurring today in many settings.

While different perceptions and perspectives are possible, the aforementioned editorial contained many factual errors. The first "class" of students in the Non-traditional Pharm.D. pathway at the University of Maryland at Baltimore included 15 pharmacists, not 22 as indicated, who began in the Spring of 1992. Since the program is self-paced and credits have been awarded through the prior learning assessment process, there is no "expected" time for graduation. We anticipate that we will have as many as ten pharmacists completing degree requirements in December of 1995. Four of these are from the original class, the rest joined the program later. Of the remaining 11 pioneers in that first class, 7 are still in the program progressing at a rate determined primarily by their schedule, and 4 have decided not to continue. From my perspective, a well-informed decision not to continue does not reflect negatively on either the program or the person making the decision.

We now have 270 students in the pathway and we admit more pharmacists yearly (i.e., 60) to our nontraditional program than any other school in the United States. Unfortunately, we do not have adequate resources to admit all qualified applicants and have to stage the admission process.

I have no idea how Mr. Berkowitz determined that each of the credits requires 75-100 hours of "work", nor exactly what someone would do with that information. Pharmacists in this pathway do work hard, but reach well defined practice outcomes - for some pharmacists in some areas this may be fast and easy; for others a substantial investment of time may be required. In any event, the goals are learning and demonstrating the application of new information and skills. I believe that this additional education will have a direct and positive impact on the quality of care for Marylanders.

The "clinical rotation" referred to by Mr. Berkowitz consists of 15 half-days at a variety of different sites. It was included in the program as a way to broaden experiential learning. Both faculty and pharmacists in the pathway provided us with feedback that highlighted the value of seeing alternative practice sites, and in particular seeing patient-specific problems that might not occur in their specific site. This is particularly valuable, for example, when community pharmacists are called upon to manage the care of patients recently discharged from an acute care setting. Evaluations from students indicate that this is one of the most worthwhile components of the curriculum. The Clinic/Institutional Assignment represents 1 credit out of a total of 10 experiential credits, and 1/30 of the entire program.

We do agree on one thing: success in this program is due to individual sacrifice and perseverance. This is true for both students and faculty. I know I have missed being at home with my family many evenings for the last three years. I clearly recognize, applaud and appreciate the contributions made by students in this pathway.

Maryland has a nontraditional pathway available; most schools have nothing. All of us directly involved have worked and will continue to work to make it the best program of its kind in the United States. We will continue to do so as long as pharmacists in the state want us to. **MP**

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At Issue

Taming Chickenpox with Routine Vaccination

Laurie J. Houser, Pharmacy Student
University of Maryland School of Pharmacy

Measles, mumps, rubella, polio, smallpox, pertussis, and diphtheria -- what do all of these maladies have in common? Once known for indiscriminately wreaking havoc upon the population of the United States, they are all "childhood" illnesses that have now been eradicated, or greatly curtailed, by the routine use of immunizations. However, one childhood exanthem still runs wild, infecting 3.9 million people in the United States every year. This highly contagious disease, which has a transmission rate of 80% to 90% among susceptible individuals within households, is the chickenpox.[1]

Caused by the varicella-zoster virus, there was little that could be done in the United States to prevent the transmission of chickenpox until recently, when a live attenuated varicella vaccine was approved by the Food and Drug Administration.

But along with the FDA's March 17, 1995 licensure of Merck & Co. Inc.'s Varivax® vaccine comes the following question: Should Varivax be a part of the routine childhood immunization schedule? It seems logical that immunization be used to corral the wild transmission of chickenpox as it is for the aforementioned childhood exanthems. Therefore, the answer to this question should be a resounding "yes." The issue of routine varicella immunization, however, is much more complicated and has led to conflicting advice from physicians and other healthcare providers.

The factor which most clouds the issue of routine vaccination is uncertainty over the length of immunity ushered by the vaccine. Opponents of routine immunization argue that in the healthy child chickenpox is a relatively benign illness, whereas in adults the disease is much more severe. A study conducted in England revealed that while they comprised only 5% of varicella cases, 35% of the deaths from varicella occurred among people between the ages of 15 and 44. Furthermore, adults over the age of 45 accounted for 39% of the varicella fatalities, while comprising only 0.5% of the varicella cases.[2] The most serious complication among adults is varicella pneumonia, for which 1 out of every 400 adults with chickenpox must be hospitalized.[3] Because the length of immunity is questionable, opponents fear that a routine childhood chickenpox vaccination will leave future generations of adults susceptible to varicella and the complications it brings to the adult population.[4] Another concern of opponents is a possible increase in herpes-zoster cases. Herpes-zoster, or shingles, is a secondary infection caused by reactivation of latent varicella-zoster virus.[5] Of those infected with chickenpox, approximately 10% to 15% experience a secondary infection when the latent varicella-zoster, which can lie dormant in sensory ganglia for years after the primary infection, is reactivated.[6]

These concerns are valid; however, the benefits of routine varicella immunization outweigh the problems that might occur as a result of potential waning immunity or potential herpes-zoster infection.

First of all, due to the nature of the illness, it will be years before the long-term effects of routine immunization on herpes-zoster will be known. However, studies of immunized children who have contacted herpes-zoster indicate that the illness is milder and occurs less frequently in vaccinated versus unvaccinated children. With natural infection, herpes-zoster occurs in childhood with a frequency of 77 cases per 100,000 person-years. In studies so far, the rate among vaccinated children is 18 cases per 100,000 person-years.[7][8][9]

Secondly, while there are no definitive answers as to the length of varicella immunity brought forth by vaccination, neither is there definitive evidence that the vaccination won't remain effective into adulthood. Oka, a live varicella vaccine similar to Varivax, has been studied in Japan for more than 20 years. Of 244 Japanese children immunized in the mid-1970's, 96 were followed into the 1990's. Among the 96, only two children contacted chickenpox. Furthermore, when 26 of these subjects underwent immunologic testing nearly 20 years after inoculation, it was discovered that their varicella antibody levels had increased two-fold from ten years earlier. The researchers suggest that re-exposure to the disease may play some role in increasing antibody levels.[10]

Although studies have indicated that the adolescent and adult immune system primary response has been less effective to varicella immunization than the immune response of children under 12 years old, they've also revealed that a second immunization can succeed in boosting an adult's antibody levels. A study of 187 adults immunized with the Oka strain revealed seroconversion levels of 82% after the first dose and 94% after the second dose. Of the adults immunized, 25% lost detectable antibodies to varicella. However, among those who did contact chickenpox after household exposure, the disease was much less severe, with an average of only 24 lesions.[11] [12] Approximately 250 to 500 lesions appear in unimmunized patients infected with varicella.[13]

It stands to reason, then, that adults could be at greater risk if routine varicella immunization is not adopted since immunization in only certain populations and demographic areas will most likely reduce the instances of wild varicella and result in fewer cases among unvaccinated children. Conceivably, these children will enter adulthood with a greater risk of contracting varicella and without the reduction in severity that vaccination would afford.

Therefore, if post-marketing studies, such as those that have been done with the measles-mumps-rubella (MMR) vaccination, reveal that vaccine-induced antibody levels may decline in certain populations, it would be more prudent to administer a second immunization to boost the antibody levels. The need for a second measles immunization came to light in the late 1980s when the number of measles cases began to soar.[14] As a result of rising measles cases, the American Academy of Pediatrics (AAP) and the Advisory Committee on Immunization Practices (ACIP) endorsed a new immunization schedule in January 1995 which recommends that a second dose of MMR be given before entering kindergarten or middle school.[15]

To combat a problem of waning immunity, such a two-dose schedule could easily be adopted for varicella as well. The issue of compliance(for all vaccinations) could be addressed by making school entry conditional upon the receipt of these immunizations, as is now done in many states, and providing compulsory vaccination clinics for those who cannot afford the shots.

While the above concerns should not be dismissed, there are several reasons why varicella immunization should be given routinely to children. To begin with, chickenpox is not always a "benign" childhood illness. According to Steven Kohn, MD, chief of pediatric infectious disease at the University of California, chickenpox is responsible for approximately 100 deaths and 9,000 hospitalizations annually.[16] Included among the complications of varicella in the healthy child are bacterial infections; herpes-zoster; Reye's syndrome; and central nervous system, pulmonary, therapeutic, and hemorrhagic complications.[17] Of the deaths and complications, most occur in children between the ages of 1 and 14, in whom 84% of encephalitis, 98% of Reye's syndrome, and 63% of deaths attributed to chickenpox occur.[18]

Chickenpox, however, is especially dangerous for immunocompromised children such as those with leukemia and other cancers requiring chemotherapy, children with human immunodeficiency virus, and asthmatic and other children receiving 2 mg/kg/day or more of corticosteroids.[19] Among these children, about one third experience disseminated disease and approximately 7% die after being infected with varicella.[20] However, the Varivax vaccination is contraindicated for most of these children.[21] This brings to light another advantage to routinely vaccinating healthy children. Routine varicella immunization will invariably decrease the transmission rate of the wild-type virus and no doubt lead to fewer cases of chickenpox among these children, for whom the disease is especially severe.

While the percentages of deaths and complications may be small in comparison to the total number of chickenpox cases, any instances of illness or death are unnecessary if preventable...and studies have shown that the majority of these cases can be prevented, or the severity greatly diminished, with routine vaccination. For example, a double-blind, placebo-controlled efficacy study of 956 children between the ages of 1 and 14, revealed a efficacy rate of 100%.[22] Another multicentered study of 3303 healthy children and adolescents resulted in an efficacy rate of 86%.[23] Because of varying vaccine lots and study conditions, numerous trials conducted in both the US and Japan have given conflicting results.

However, a recent study of 1,105 healthy children followed for two years after inoculation with a vaccine manufactured in 1991, which was of higher potency than that used in many previous studies, revealed a breakthrough rate of less than 1%, reported C. J. White, MD, former senior director of clinical research at Merck and current consultant to the firm, at the February 1995 meeting of the ACIP.[24] Even among those for whom Varivax fails, the vaccination appears to have benefit. In a clinical survey of 150 children from four pediatric practices, 58 of whom had been vaccinated against chickenpox, the vaccinated children experienced less fever, significantly fewer lesions, and recovered in a shorter time periods than the 92 who had not been immunized.[25] Analysis of the previously-mentioned multicentered survey gave similar results. Of the 3,303 children studied, 62 cases of breakthrough vaccination had been reported within one year of vaccination. The median number of lesions among these children was 32, and in most cases, their symptoms were clinically milder.[26]

In addition to a reduction in mortality and morbidity, the routine varicella vaccination is beneficial from a cost standpoint. Taking into consideration medical costs and lost wages due to work loss by parents and other caretakers, a study published in 1994 revealed that society will experience a net savings of $384 million with the adoption of a routine varicella vaccination. The decision analysis model assumed a vaccination efficacy rate of 94% and a 97% coverage rate in pre-school children.[27] Furthermore, no deaths and few adverse effects have resulted from the vaccination. About 7% of children and 8% of adults develop a mild rash, and approximately 20% of children and 25% to 35% of adults develop transient pain and tenderness around the site of injection.[28] [29]

Despite the questions surrounding long-term immunity and herpes-zoster transmission, the vaccine's benefits make routine childhood immunization against varicella the appropriate strategy. Future studies will no doubt address the issues brought forth by opponents of routine varicella vaccination and more likely than not lead to improved vaccines and administration schedules. In the meantime, today's children, as well as their parents, should not have to suffer through a preventable illness. Deemed "minor" or not, no amount of preventable suffering is justified. And while it may be "benign" in most cases, chickenpox is a disease that can lead to serious illness and death in not only ill children, but healthy children as well. Regardless of whether or not a second booster is required, the varicella vaccine should be administered routinely, for it will result in substantial savings to society, both in terms of money and quality of life. **MP**

References available upon request.

Continuing Education Quiz

January/February 1996 -- Losartan/Moexipril

This month's questions are taken from the article on new antihypertensives that appears in this issue. Circle your answers to the following questions and mail the entire page to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. There is **no charge** for this quiz for MPhA members (non-members $5.00). The completed quiz for this issue must be received by February 28, 1997. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly.

Name ______________________________

Address ______________________________

City/State/ZIPCode ______________________________

1. The dosage regimen for Cozaar is:
   a. 10mg four times a day
   b. 25mg three times a day
   c. 50mg daily
   d. 100mg twice a day

2. In one study, the estimated percent of patients placed on antihypertensive therapy who discontinued their medication after one year was:
   a. 10 percent
   b. 25 percent
   c. 50 percent
   d. 70 percent

3. The primary enzyme responsible for the metabolism of angiotensinogen is
   a. anginase
   b. cytochrome
   c. plasmin
   d. renin

4. Which of the following side effects is seen with patients taking losartan to a greater extent than with those receiving the placebo?
   a. Angioedema
   b. Cough
   c. Dizziness

5. Patients taking Cozaar, Hyzaar and Univasc should not use which of the following OTCs without first consulting their physician?
   a. Salt substitutes
   b. Calcium supplements
   c. Aspirin
   d. Antihistamines

6. The boxed warning in the package insert for all three drugs listed in question #5 refers to:
   a. cancer
   b. pregnancy
   c. agranulocytosis
   d. orthostatic hypotension

7. Aldosterones is responsible for the:
   a. exchange of potassium for sodium in the kidney
   b. stimulation of the vasomotor center
   c. conversion of angiotensin I to angiotensin II
   d. direct constriction of vascular smooth muscle

8. The therapeutic action of losartan is due to its ability to:
   a. block angiotensin II receptor sites
   b. inhibit the conversion of angiotensin I to angiotensin II
   c. decrease the formation of prostaglandins
   d. increase the formation of bradykinin

9. Losartan has a long duration of action because it:
   a. is available in a controlled release dosage form
   b. has an innately long biological half-life
   c. is metabolized into a long acting metabolite
   d. is highly protein bound

10. The therapeutic action of moexipril is due to its ability to:
   a. block angiotensin II receptor sites
   b. inhibit the conversion of angiotensin I to angiotensin II
   c. decrease the formation of prostaglandins
   d. increase the formation of bradykinin

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Placing an Ad

Have something to sell, rent, or trade? Need a pharmacist? Looking for a new position? MPhA members can place a classified ad in *The Maryland Pharmacist* for *free*. MPhA will remove member ads after six months unless otherwise notified by the member. Non-members may also place a classified ad. The ad placement charge is $10 for a maximum of 50 words plus 50 cents per word greater than 50. To place an ad, call MPhA at (800) 833-7587.

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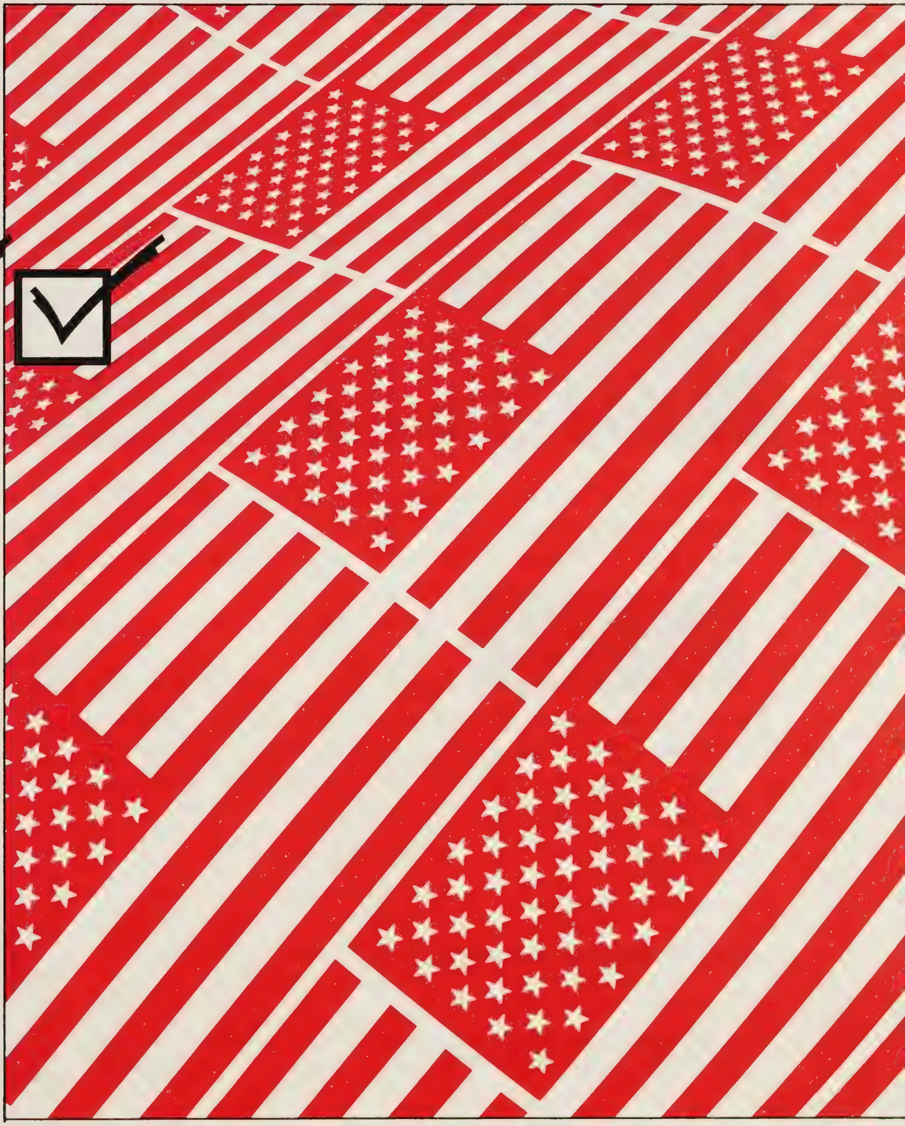

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MARYLAND PHARMACIST

The Official Publication of The Maryland Pharmacists Association

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MPhA President Jim Tristani looked at the recent MPhA survey of pharmacists and isn't wonders about expectations versus reality.

5 Recognizing Pharmacy Excellence

Each year, MPhA recognizes outstanding pharmacists through a variety of awards. Here's your opportunity to help acknowledge the best or the best.

11 Interactions

The School of Pharmacy's service to the profession doesn't just end with educating tomorrow's pharmacists. Tony Tommasello explains some of the unique programs that directly benefit the professional community.

14 Herbal Medicine - Part Two

Continuing from last month's issue, MPhA member William Skinner provides additional insight and tips on how pharmacists can take advantage of the increased interest in herbal and natural remedies.

17 1996 Board of Pharmacy Elections

Every Maryland pharmacist has the opportunity to vote in this year's elections of two Maryland Board of Pharmacy Commissioners. Don't forget to return the ballot on page 23 by April 10!

26 At Issue: OTCs

Are over-the-counter medications the best solution for meeting consumers perceived self-medication needs? Pharmacy student Jennifer Weiland looks at this billion dollar a year industry.

33 Continuing Education

This month, we feature a review of lice treatments. Don't forget to complete and return the CE quiz on page 38! It's *free* for all MPhA members.

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President's Commentary

Instant Gratification

A funny thing happened on the way to our Mid-Year meeting. Responding to a four-page survey on MPhA's programs and services, most pharmacists wrote down what additional things MPhA could do to give additional value for their annual dues investment. The MPhA Board of Trustees and the Strategic Planning Committee reviewed these ideas. While many of the ideas will involve some restructuring and changes in the organization, there were some that I think I can take care of right away.

These included the suggestions that MPhA:

- Tackle economic issues as it did in the past.
- Pass legislation to repeal federal anti-trust laws that allow prohibit pharmacists from getting together and talking about third-parties.
- Increase HMO, insurance company, PBM and Medicaid dispensing fees
- Negotiate dispensing fees with third-parties
- Tell pharmacists which contracts they should or should not sign
- Stop multi-tier pricing
- Institute legal actions to stop fee cuts and get pharmacists collective bargaining rights
- Be available to answer important questions like...
    - -- What is my Medical Assistance Provider numbers?
    - -- When is the Alumni Banquet the School of Pharmacy is giving.. I lost my three notices?
    - -- Can you track my CE credits in case I need them at renewal time?
    - -- Can you tell me the name of the little white tablet with two squiggly lines?

To our members who submitted or agree that MPhA should do all these things, *all* your wishes have been granted!

NOT!!

James Tristani, P.D.
1995-96 MPhA President

Believe it or not, the Maryland Pharmacists Association is not your mother. We cannot put your CE certificates away for you nor will we tell you what time to come to dinner. Try as we can, MPhA does not have all the answers nor do we have all the solutions to every problem that you will experience as a pharmacist. If you needed to have Medical Assistance solve a problem you're having with on-line claims adjudication, would you call the State Board of Pharmacy? Of course not! But you would and do call MPhA.

As to the dozens of economic issues we are asked to or demand to resolve the laws are quite clear; 90% of the things listed across the page would probably net us one to five years in the nearest federal facility. The other 10% might be possible with a budget of five to ten million dollars; unfortunately, MPhA's budget is less than $350,000.

There is one more item we are not. We are not the organization of one special group of pharmacists. The idea we are an independent owner group or a Baltimore only group is nothing more than a leftover myth from the 1970's. Just as the Board of Pharmacy is rewriting the Pharmacy Practice Act, MPhA is re-engineering what it is and does.

Let me correct that last statement. We are one special group of pharmacists -- *MPhA members!* As our Strategic Planning Committee takes on the task of developing our new goals and framework, it is being done with an eye to serve best the people who pay dues. MPhA cannot longer allow its resources to be squandered on issues that divide us. Nor can we waste our time helping pharmacists who have little or no interest in belonging but do expect us to be there when they have a problem or questions.

I think you're going to like the "new" MPhA. **MP**

Honoring Achievement

The MPhA Awards Program

Howard Schiff, P.D., Chairman
MPhA Past Presidents Council

Each year, the Maryland Pharmacists Association recognizes professional excellence through a series of awards. To nominate a pharmacist for one of the awards described below, complete the official Award Nomination Form on page 7 of this issue. The Award Nomination Form information should be clear and legible. Forms should be sent to: **Award Nominations**, c/o Maryland Pharmacists Association, 650 West Lombard Street, Baltimore, Maryland 21201-1572.

All nominations will be considered by the Past Presidents Council. The Council is responsible for selecting the recipients and their decision is final. Award recipients will be notified in advance of the award's presentation. For consideration, all nominations **must** be received no later than April 30, 1996.

MPhA Honorary President

About the Award An honorary position on the Board of Trustees given to a person who has worked for the MPhA or Maryland pharmacy over a long period of time. The recipient receives a plaque and is an official, ex-officio member of the Board for one year.

Who is Eligible Any long standing contributor to the profession or the Association. The honoree need not be a pharmacist or a member of MPhA.

1995 Honoree Maribeth Porter for her six years of service to MPhA as office manager.

Past Honorees:

1970	Irving Cohen
1971	H. Nelson Warfield
1972	Wilfred Gluckstern
1973	Morton Schnaper
1974	Harry Schrader
1975	Frank Block
1976	Morris Lindenbaum
1977	I. Earl Kerpelman
1978	Paul Reznek
1979	Joseph Kaufman
1980	Victor Morgenroth
1981	John Krantz, Jr.
1982	William Kinnard, Jr.
1983	Alexander Mayer
1984	Joseph Dorsch
1985	Peter Lamy
1986	William Heller
1987	Bernard Lachman
1988	Walter Weglein
1989	James Cragg
1990	Paul Freiman
1991	Mark Golibart
1992	Betty Alpern
1993	Isabel Futeral
1994	Ralph Small
1995	Maribeth Porter

Wyeth-Ayerst Bowl of Hygeia Award

About the Award The Bowl of Hygeia recognizes a pharmacist who has performed outstanding services to the community in any area, with a particular emphasis on non-pharmacy contributions. The recipient receives a plaque, a lapel pin, and a trip to meet with other Bowl of Hygeia recipients.

Who is Eligible Any Maryland pharmacist who has not already received the Bowl of Hygeia.

1995 Award Recipient R. Dennis Hager, P.D., Millington, for his service as Mayor and other community leadership activities in Kent County.

Past Honorees:

1964	Simon Solomon
1965	Norman Levin
1966	Gordon Mouat
1967	Harold Goldfeder
1968	Victor Morgenroth
1969	Clinton Englander
1970	I. Earl Kerpelman
1971	Charles Spigelmire
1972	Morris Bookoff
1973	Paul Renek
1974	James Truitt, Jr.
1975	Anthony Padussis
1976	S. Ben Friedman
1977	Joseph Dorsch
1978	Henry Seidman
1979	Paul Freiman
1980	Donald Fedder
1981	James Gudling
1982	Samuel Goldstein
1983	Nathan Schwartz
1984	Philip Cogan
1985	Marvin Freedenberg
1986	Ronald Proudfoot
1987	Oscar Schapiro
1988	Marvin Oed
1989	Bennett Bozman
1990	Jerome Fine
1991	Irving Fink
1992	Robert Martin, Sr.
1993	James Rutten
1994	Ernest Gregg
1995	R. Dennis Hager

Seidman Distinguished Achievement Award

About the Award Created to honor the major impact on Maryland pharmacy by Henry Seidman, this award is presented for outstanding service by a Maryland pharmacist to the pharmacy profession during *either* the past year or over a period of years. The recipient receives a plaque and clock.

Who is Eligible: Any MPhA pharmacist member who meets the criteria of the award.

1995 Award Recipient: Ralph Shangraw, Ph.D., Baltimore

Past Honorees:

1980	Henry Seidman (posthumous)
1981	Melvin Rubin
1982	Morris Cooper
1983	Charles Spigelmire
1984	Paul Freiman
1985	Frank Block
1986	Bernard Lachman
1987	Charles Spigelmire
1988	Donald Fedder
1989	Mayer Handelman
1990	Milton Sappe (posthumous)
1991	Milton Moskowitz
1992	Ralph Quarles
1993	Peter Lamy
1994	Ronald Sanford
1995	Ralph Shangraw

Hoechst Marion Roussell Distinguished Young Pharmacist Award

About the Award Awarded to a pharmacist who has graduated within the past nine years and has made a significant contribution to the profession through service in a local, state, or national pharmacy organization. The recipient receives a plaque.

Who is Eligible Any MPhA pharmacist member who graduated from pharmacy school in 1987 or after.

1995 Award Recipient Mark Sanford, P.D., Catonsville.

1987	Thomas Williams
1988	Brian Sanderoff
1989	Ilene Zuckerman
1990	Gary Magnus
1991	Beverly Yachmetz
1992	Kathleen Gauthier
1993	Kathrin Kucharski
1994	David Miller
1995	Mark Sanford

Dupont Innovative Practice Award

About the Award Established in 1993, this award aims to recognize forward-thinking pharmacists who have expanded their practices into new areas. This may include adding a new service, restructuring a pharmacy and its current services, or developing a completely new practice. The award recipient receives a plaque, a medal, and a framed water-color sketch.

Who is Eligible Any MPhA pharmacist member who meets the criteria of the award.

1995 Award Recipient Irwin Rosenberg, P.D., Bethesda.

Past Honorees:

1993	Beverly Yachmetz
1994	Phillip P. Weiner
1995	Irwin Rosenberg

MP

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Maryland Pharmacists Association

Award Nomination Form

To nominate a Maryland pharmacist for one of MPhA's annual "Recognizing Pharmacy Excellence" awards, this form must be completed in its entirety and returned to the Maryland Pharmacists Association no later than April 30, 1996. All nominations will be held in strictest confidence by the MPhA Past Presidents Council which is responsible for selecting the award recipients. The decision of the Council is final. Award recipients will be notified in advance of the award's presentation.

Please consider the following nominee for: *(check one)*

☐ Seidman Distinguished Achievement Award
☐ Distinguished Young Pharmacist Award
☐ Dupont Innovative Practice Award
☐ Wyeth-Ayerst Bowl of Hygeia
☐ MPhA Honorary President

Nominee ____

Home Address ____

Home City/State/ZIPcode ____

Current Place of Employment/Practice ______________________________

Home Telephone Number ____________________ Work Telephone ______________

Name of Nominator ____

Nominator's Telephone Number ______________________________

Attach a current resumé or curriculum vitae for the nominee that shows their professional and personal achievements. This information is essential for the Past Presidents Council to make its decisions on which candidates will become recipients of the "Recognizing Pharmacy Excellence" awards. In addition, the nominator should attach a brief letter explaining why the nominee is worthy of receiving this award.

Return the completed form to:
Award Nominations, c/o Maryland Pharmacists Association
650 West Lombard Street, Baltimore, Maryland 21201-1572

1996 Membership Investment Form

Maryland Pharmacists Association

Keep this magazine and lot's more information coming to you every month. Joining MPhA is as simple as checking a few boxes. Just write your name and address in the space provided, check a couple of boxes, slip it in an envelope and drop it in the mail of FAX it to (410) 727-2253. **It's that easy.** (If you're not sure if you are currently a member, look at the mailing label on the front of this issue or call us at (800) 833-7587).

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Maryland Pharmacists Association

	Category	Dues
☐	Pharmacist	$ 150.00 *

* Includes membership in your choice of one of the local pharmacists association listed below.

Local Pharmacists Association

☐ Allegany County
☐ Anne Arundel County
☐ Baltimore Metropolitan
☐ Eastern Shore Pharm Society
☐ Garrett County
☐ Frederick County
☐ Prince Georges/Montgomery County
☐ Southern Maryland (Calvert/Charles/St. Marys)
☐ Upper Bay (Harford/Cecil)
☐ Washington County

Voluntary Contributions

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☐	**Pharmacists Rehabilitation Committee** Supports chemically impaired pharmacists with recovery and advocacy resources.	$15
☐	**MPhA Scholarship Fund** Provides for MPhA's scholarship program for University of Maryland pharmacy students.	$15
☐	**Kelly Memorial Fund** Helps maintain the MPhA headquarters and B. Olive Cole Pharmacy Museum.	$10
☐	**MPhA Survival Fund** A defense fund established for legal action necessary to protect the profession's interests.	$25

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Maryland Pharmacists In the News

Ruth Blatt, pharmacy manager of NeighborCare Pharmacies in Reisterstown and **Tim Lubin**, pharmacy manager of NeighborCare Pharmacy in Towson, were two of only 30 pharmacists selected to participate in the APhA/SmithKline Beecham Community Pharmacy Management Program held recently at the University of Wisconsin at Madison. This program provides pharmacists the opportunity to gain information and insights that will help them provide superior service to their patients.

The APhA/SB Community Pharmacy Management Program is an intensive, seven-day management symposium presenting a curriculum from the University of Wisconsin at Madison College of Pharmacy and the College of Business. This year's educational sessions included: communication skills, marketing concepts, innovative practices in pharmacy, strategic planning, customer relations, promotion, quality assurance systems, management information support systems, and motivation skills for pharmacy managers.

The 30 participants were chosen by the program's Advisory Committee from among numerous pharmacist applicants. The program is designed to bring leaders in community pharmacy together in a university environment for concentrated study, sharing and growth. ℞

Melvin Weinswig, Dean; MPhA members Tim Lubin and Ruth Blatt, and Alan Hanson, Professor, Wisconsin School of Pharmacy.

After 17 years as Director of the Professional Experience Program at the University of Maryland School of Pharmacy, **Marvin Oed** will be retiring at the end of the 1996 school year to take on new challenges.

Marvin Oed

A mainstay of Maryland pharmacy, Marvin was honored by the Association in 1988 with the Wyeth-Ayerst Bowl of Hygeia, the highest professional pharmacy award for community service. He has been an active supporter of the American Heart Association, the American Diabetes Association, and served on Governor Shaefer's Advisory Council on High Blood Pressure and Cardiovascular Risk Factors. Practically every Maryland graduate worked directly with Marvin and his staff to select PEP sites. ℞

Do you know of a Maryland pharmacist who deserves recognition? Maybe it's someone who has been featured in a local newspaper or contributed to their community in some way. If so, we want to feature them in this *Maryland Pharmacist* column.

Just send us a brief description of their activities and a photo to our offices at 650 West Lombard, Baltimore MD 21201-1572. MP

Anthony Tommasello, Director, Office of Substance Abuse Studies
Associate Professor, Department of Pharmacy Practice, UMAB School of Pharmacy

This is an information age. Pharmacists have created the professional identity of "drug expert" and have risen to the challenge of fulfilling that image in an ever expanding environment of drug information. Managing the increasing volume of new knowledge requires not only a grounding in the familiar territory of the basic sciences that comprise the pharmacy curriculum, as well as ongoing continuing education in these critical areas of theory and fact, but a courageous spirit of discovery of the new technologies needed to acquire, assimilate, and disseminate this resource.

The Office of Substance Abuse Studies (OSAS) is a drug abuse information, education, and training center that functions as the major source of chemical dependence expertise in Maryland for pharmacists. Its main function is to provide substance abuse and addiction information in order to prevent and treat this devastating health problem and conduct research to improve future efforts in these areas. OSAS administers the University Interprofessional Drug and Alcohol Program and is instrumental in the operations of the Pharmacists Rehabilitation Committee, which is jointly sponsored by the Maryland Pharmacists Association, the Maryland Society of Health Systems Pharmacists, and the School of Pharmacy. In addition to providing services to impaired pharmacists in the state, the committee has developed continuing education courses in the area of chemical dependency for MPhA.

To meet its goals of education, training, and research, OSAS provides a library service to assist in substance abuse literature research and retrieval. OSAS maintains an online drug abuse information database and publishes a quarterly newsletter, PharmAlert. Education and training go hand-in-hand and start with students enrolled in the Pharm.D. Program. Students can participate in an elective course on chemical dependency, clinical rotations, or interdisciplinary research projects. Students who want more in-depth exposure can participate in two other committees coordinated through OSAS: the Student Committee on Drug Abuse Education (SCODAE) and the Students for Drug Awareness and Prevention (SDAP).

SCODAE's role in community service is based on the premise that information on pharmacology and other drug related topics is a basic educational need that ultimately furthers the goal of prevention of substance abuse. This group of pharmacy students interact with health professionals, such as physicians, pharmacists, and nurses, along with other professionals, such as teachers, ministers, and law enforcement personnel to meet their educational needs. However, most of the presentations are targeted to middle school (grades 7 through 10) students. What started out as one-hour drug talks soon evolved into a five part course that provided information on drugs in five blocks, each one devoted to a specific topic. Training for student volunteers is accomplished through an eight-hour instructional course along with field experiences. Students receive academic credit for their experience in addition to the personal satisfaction and rewards of participating in community service.

At the campus level, prevention activities are conducted by the SDAP group. SDAP is an interprofessional student group organized under the Interprofessional Drug and Alcohol Program faculty. Its members are trained in the area of substance abuse and chemical dependency. The mission of SDAP is to prevent alcohol and drug abuse and to support recovery. This student oriented program conducts alternative activities (such as "alcohol free" bars and recipes) as well as information dissemination. This program endorses moderate alcohol use through a "0,1,3" campaign (0 drinks if pregnant, recovering, or scheduled for clinic within 24 hours, 1 drink per hour, no more than 3 drinks per occasion) and strives to make non-drinkers feel comfortable in the college environment. Members of

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- Rehabilitation Committee
- Liaison efforts with other organizations
  - the Board of Pharmacy
  - Schools of Pharmacy
  - MD Medicaid
  - Third Parties
- Scholarships
- Professional Awards
- Cole Pharmacy Museum
- PharmPAC
- Rx Vanity Plates

To Balance the Equation, We Just Need You

SDAP are actively seeking opportunities to take their program to the community and promote wellness and health maintenance as regards alcohol, tobacco, and other drug use.

The work that OSAS has accomplished in educating the public about substance abuse prevention has been nationally recognized. Over the years, OSAS has received federal support from groups such as the Fund for the Improvement of Postsecondary Education and the National Institute on Drug Abuse and state support through the Maryland State Department of Education and the Addictions Services Administration.

OSAS is a center for expertise in the field of drug abuse and chemical dependence, and provides an environment in which students of this field can gain valuable experience in the clinical, research, and service aspects of pharmacy practice. As SCODAE, the seed program of OSAS, celebrates its 25th anniversary of continuous community service, there are dramatic changes taking place in the addictions field. Technological advances in the area of informatics, budgetary constraints, and shifts in the spending priorities of the state and federal governments, a resurgence of drug abuse among youth, and the ever present challenge of addictions in the profession, require new approaches and bold action. OSAS continues to create innovative community service programs (interprofessional community substance abuse prevention teams), participate in addictions research (policy issues related to professional recovery programs, and substance abuse treatment evaluation), and develop unique clinical experiences for students (clinical rotations with the University of Maryland Medical System alcohol consult team and placements at drug abuse treatment centers.) **MP**

For more information on the Office of Substance Abuse Studies and SCODAE, contact Dr. Tommasello at the University of Maryland School of Pharmacy by calling (410) 706-7513.

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Lawful Herbal Medicine

William J. Skinner, R.Ph., J.D.

While there is a great amount of scientific activity on the use of herbal medicines, it is rarely reported in traditional pharmacy and medicine journals, partly because of the wacky suspicion about any people who believe in plant medicine. The increasing use of herbal remedies by the American public cries out for this information to become part of the pharmacists' background data.

A growing recognition among environmentalists and a part of impetus for research in phytomedicine is the growing scarcity of plant materials as the world becomes more and more populated and the wild areas are destroyed without knowing what plant drugs are being destroyed. We may be wiping out remedies that have been in the making for a million years and doing great harm to our future health.

Practically speaking, a pharmacist must question whether he or she can earn a living from the knowledge of herbal remedies. It is just another area where there are not strong possibilities of economic gains? After all, the regulatory system we have created in the U.S. to protect the general public from "quackery" effectively supports keeping drug-type claims off of herbal remedies. Whether a living can be made in this field or not, it impacts health care since many Americans are using herbal remedies anyway. At the same time there is some basis for a reasonable expectation that the regulatory scheme in the United States may change in the future to permit low cost herbal remedies to be tested by less strenuous regulatory requirements, perhaps as the German Commission E has done, so that the poor, the traveler and the immigrants can be served. However, we all know that pharmacists are not now getting paid for what they know how to do already, but many do guide patients in the use of prescription medication. Thus, imposing a whole new theory of herbal care and the attendant counseling responsibilities may not make many pharmacists rich.

But, consider the alternatives that are part of the larger picture. For example, in the past thirty years, since 1965, when Medicare went into effect, the costs of health care in this country have grown to where it consumes 15 to 18 percent of the gross national product. At the same time Medicare and Medicaid grew for 30 years, the Health Professions Education Assistance Act and other laws pumped billions of dollars into health professions education, including the financing of the "clinical pharmacy" movement. Although pharmacy was dropped from health professions support in the late 1970's and early 1980's because of the internal bickering among factions of pharmacy and because of encroachment into medical fields, the growth in the number of pharmacy schools continues as there are now more schools than when the capitation and special projects dollars for pharmacy education dried up.

On the socio-political scene, the 104th Congress is trying to cut $270 billion in spending from previously expected expenditures in Medicare and Medicaid over the next seven years because a majority of its members have realized that continued spending will require more and more taxes to prevent the programs from going bankrupt. A majority in Congress does not believe that Americans have the stomach to spend 20 to 30 percent of the gross national product on more and more of the same kind of expensive health care.

Modern bullet medicines take years to develop and cost an average of $359 million each.[1] FDA takes 20 months or more to approve the New Drug Applications it receives although the law gives them only six months.

During the past three years, the European-American Phytomedicines Coalition (EAPC), a group of European and U.S. companies, has filed three citizen petitions at FDA to get the agency to allow the sale of herbal remedies that are sold in Europe. The first petition was filed in July 1992 asking FDA to change its policy that refuses to recognize foreign marketing histories of well known botanical ingredients. FDA is still studying this petition.

A second petition was filed in June 1994 to get FDA to recognize valerian root (*Valeriana officinales, L.)* as a nighttime sleep aid. This petition pointed out that 40 million Americans suffer from chronic sleep disorders, that current prescription drugs like hypnotics and tranquilizers may be addicting, unlike valerian. And the approved prescription drugs reduce REM sleep and cause residual drowsiness, which valerian does not do. Valerian is approved in Germany, France and England and it was sold in the US as a tincture by Eli Lilly & Company until 1985. FDA is still reviewing this petition.

The third petition was filed in May 1995 to ask FDA to approve ginger to prevent nausea and vomiting. Similar data was supplied to FDA, including the fact that 100,000 tons of dried ginger are used every year without reports of ill effects and deaths. FDA has not responded.[12] Some wonder if it ever will.

If we continue spending on Medicare and Medicaid and health professions education for another thirty years at the rates we have spent in the past, it is inevitable that more and more

Sources for Additional Information

Journals

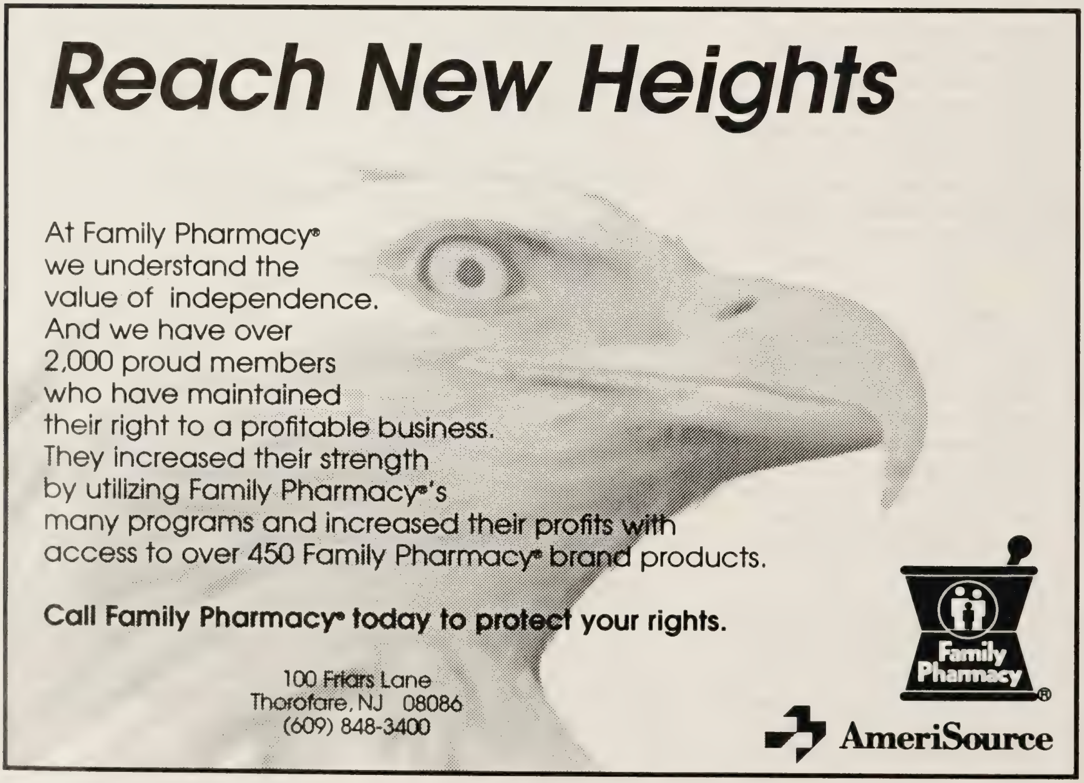
1. **Herbalgram**, The Journal of the American Botanical Council and American Herb Research Foundation. $25/year, published quarterly, from ABC, P.. O. Box 201600, Austin, TX 78720. This one contains departments, including Research Review, on the latest scientific results of herb research, Research/World News, Market Report, Book Reviews, and features on many interesting herbal topics.
2. **The Herbal Greenpages**: An Herbal Resource Guide, Edited by Maureen Rogers, Herb Growing & Marketing Network, P. O. Box 245, Silver Spring, PA 17575, comes with **The Herbal Connection**, bimonthly, a collection of articles concerning growing, handling, marketing, cooking, trade shows, etc. $60.00 per year for listing in the resource guide and a subscription to the bi-monthly. (717)393-3295. It is a good way to see the scope of the herb business.
3. **The Herb Quarterly**, $24.00/year, from Long Mountain Press, 223 San Anselmo Ave., #7, San Anselmo, CA 94960. Interesting feature articles and advertisements in the field of herbs, health and related products and services.
4. **Phytotherapy Research**: An International Journal, bimonthly for 8 issues a year, published by John Wiley & Sons, Ltd, Baffins Lane, Chicester, Sussex PO19 IUS, UK, $595.00/year. Typically chemical analysis articles and review papers. It has a patents alert on applications in Japan, European, France, Chinese, German, and PCT international.
5. **Planta Medica**, Natural Products and Medicinal Plant Research, edited by Adolph Nahrstadt, for the Society for Medicinal Plant Research, bimonthly, Thieme Medical Publishers, 381 Park Avenue, South, NY, NY 10016, 426 DM, plus 24 DM mailing to U.S. from Münster. Contains review articles, e.g., "Quality of Gingko Preparations" by O. Sticher in Vol. 59, No. 1 (1992).
6. **Phytomedicine**, International Journal of Phytotherapy and Phytopharmacology, editors are Farnsworth and Wagner, 4 issues per year for 366 DM, VHC Publishers, Inc., 303 N.W. 12th Avenue, Deerfield, Beach, FL 33442-1705. Contains good review articles with top research citations. New in 1994.
7. **Medical Herbalism**, A Clinical Newsletter for Clinical Practitioners, quarterly of 16 pp., $29.00/year, P. O. Box 33080, Portland, OR 97233, $75.00 for all back issues.
8. **Newsletter** of the American Herb Association, P. O. Box 1673, Nevada City, CA 95959, $20.00/year.
9. **The Herb Companion**, bimonthly, Interweave Press,Inc., 201 East Fourth St., Loveland, CO 80537, $24.00/year
10. **The Business of Herbs**, bimonthly, R.R. 2, Box 246, Shevlin, MN 56676-9535, $20.00/year
11. **The Protocol Journal of Botanical Medicine**, P. O. Box 108, Harvard, MA 01451, $96.00/year, edited by Svevo Brooks. One of the newer publications.
12. **Journal of Natural Products (Lloydia)**, published by the American Society of Pharmacognosy and the Lloyd Library and Museum, monthly, edited by A. Douglas Kinghorn, College of Pharmacy, University of Illinois at Chicago, 555 31st St., Downers Grove, IL 60515, $225.00/year. Review articles and book reviews.
13. **Journal of Herbs, Spices, & Medicinal Plants**, quarterly, edited by Lyle E. Craker, Food Products Press at Haworth Press, 10 Alice Street, Binghamton, NY 13904-1580, $24.00/year. Started in 1992 and contains articles on growing, analyzing, processing and reviews of subject plants. Basic research in the field by graduate students and seasoned scientists.
14. **Herbs, Spices and Medicinal Plants: Recent Advances in Botany, Horticulture, and Pharmacology**, edited by Lyle E. Craker and James E. Simon, Food Products Press at Haworth Press, 10 Alice Street, Binghamton, NY 13904-1580, Vol. 1 started in 1986 and this is a series of four volumes in 1995. Contact publisher for prices.

tax money will be required. Also, consider that medical scientists acknowledge that 80 percent of all visits to physicians in the United States are for stress related or life-style related diseases. In other words, in only about 20 percent of the cases will a modern chemical bullet medicine be of specific help. The remaining overwhelming percentage of visits may result in prescriptions for pharmacists to fill in a community pharmacy, chain store, managed care pharmacies, mail order pharmacies and the remaining private practice pharmaceutical care locations, but will these improve health or just add to the costs of health care as we have known it?

Rather than choosing to spend an ever increasing amount of our resources on this kind of health care, it makes sense that we try to find some ways to treat stress and emphasize life-style changes. If we do not, we are essentially determining that we are comfortable with spending more and more on the less essential causes of poor health. We need to find less expensive treatments.

One way to find a solution to what must be done is to complete the necessary scientific research on these natural herbal remedies, and to do this a new standard for approval must be passed by Congress. There need not be the same approval system for herbal remedies as for chemical medicine if we are treating stress and life-style diseases. People are killing themselves anyway out of ignorance. The founding documents of the U.S. never promised a perfectly healthy life, only an equal opportunity to find it. One has to find this by themselves, on their own. And a U.S. citizen ought to have some responsibility for their own health.

How does a pharmacist get ready for this future of lawful herbal pharmacy? How do you learn more about natural remedies, herbs, teas, immune stimulants known by American Indians, German herbal remedies, and good common sense first aid made from green medicine. That will be the topic of Part III of this article, appearing in the May/June issue of *The Maryland Pharmacist*. **MP**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The 1996 Board of Pharmacy Elections

Ernest Testerman, P.D., President-Elect
Maryland Pharmacists Association

In 1992, the Maryland General Assembly changed the laws governing the appointment of pharmacists to the Maryland State Board of Pharmacy. The new laws now enable all pharmacists in the state to have the opportunity to nominate and vote for the person they feel would best represent their interests as a Board Commissioner.

Last fall, the Maryland Pharmacists Association began the lengthy process of obtaining nominations from individuals interested in serving on the Board of Pharmacy. A call for nominations was issued to pharmacists through this magazine and through the MPhA newsletter. Seven pharmacists were nominated -- four for the seat traditionally held by a chain pharmacist and three for the seat traditionally held by an institutional pharmacist.

Each of these seven pharmacists were invited to speak and present their credentials and opinions before the pharmacy community at the February 1996 MPhA Mid-Year Meeting in Annapolis. They also wrote a brief description of their goals and opinions for you, the voting pharmacist, so that you could best judge their qualifications as a Board of Pharmacy Commissioner.

It is now your turn to take part in the selection process!

Pharmacists licensed and residing in Maryland received a this month's issue of *The Maryland Pharmacist*. On the next several pages appear the written statement from each of the seven candidates. On page 23 is a tear-out ballot for you to use in voting. Please review each of the candidates' statements and then turn to the ballot page. For the chain seat, select up to three names of those candidates you feel would be best qualified for the position. For the institutional seat, select only one name. Once you have finished voting, fold your ballot with the return address facing out, add a stamp, and mail your vote to arrive at MPhA by April 10, 1996.

After the voting period has ended, the MPhA Canvassing Committee will tally the votes. The names of the three candidates who receive the most votes in both categories will be submitted to the Governor. The Governor, by law, makes the final selection from the submitted list.

Each of the seven candidates presented here represent some of the best and brightest of our colleagues. I believe that any of them would be an exceptional addition to the Maryland State Board of Pharmacy.

Voting Instructions

1) Use the ballot on page 23.

2) Select up to three (3) different names for the chain seat by *checking* the box next to the last name of the candidate on the enclosed ballot. You may vote for less than three names. Your ballot will be invalidated if you check more than three (3) names.

3) Select only one (1) name for the institutional seat by *checking* the box next to the last name of the candidate on the enclosed ballot. Your ballot will be invalidated if you check more than one (1) name.

4) Fold your completed ballot so that the mailing address faces out. Mail the ballot so that it arrives at MPhA no later than April 1, 1996.

5) A Canvassing Committee of two MPhA members and two non-members will count the ballots.

6) The names of the three candidates who receive the most votes will be sent to the Governor in order of vote count. For example, if Candidate A receives 100 votes, Candidate B receives 200 votes, and Candidate C receives 225 votes, the list will appear like this: Candidate C, Candidate B, Candidate A.

7) The list of candidates sent and the final appointment will be reported to the pharmacy community in an upcoming MPhA publication **MP**

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Board of Pharmacy Candidates: Seat #1

Stanton G. Ades

13 Hambleton Court
Baltimore, MD 21208

Graduated
1974, University of Maryland
Practice
Community/Chain

I would like to thank you for this opportunity to serve on the Maryland State Board of Pharmacy. I feel the experience I have gained in my twenty-one year professional career provides an opportunity to demonstrate the flexibility, creativity, and responsibility required to propel our profession in the twenty-first century.

The health care revolution of the 1990's has created enormous challenges for every participant in the health care delivery system, for providers, recipients, and payers alike. In my opinion, the only way to ensure long term survival for all participants is through a seamless integration of health care services.

Currently, health care services are being administered in a vacuum, with little communication between various providers. When diagnosis is made, there is seldom access to a patient's total history, and medications are prescribed without the benefit of a complete drug regimen review. Pharmacists dispense medication with no more than an assumption of a diagnosis. The opportunity for pharmacy: to demonstrate how real dollars can be saved through utilization and compliance management.

Fortunately, the health care delivery system has heard the wake up call. Large number of doctors, hospitals, long term care institutions, home health providers, and pharmacists have the experience and knowledge to make the system work. Hospitals and long term care institutions must partner with primary care physicians and interchange information on a real time basis to maximize cost efficiencies. Physicians recognize that pharmacists can assist them in selecting less costly/more effective drug therapy, and most importantly monitor their patients to assure compliance, thus providing the outcomes data the health care system needs. The most logical step to providing these services is to provide them at the point of service, eliminating wasted time and ensuring the highest degree of health care at the lowest cost.

Today's pharmacist must seek new roles in the health care delivery system which emphasize patient care management, rather than simply the distribution of drugs. What is needed to accomplish this -- to make today's pharmacist ready to accept this challenge? The basic elements are: a solid clinical base from which to influence therapy selection and manage outcomes, training in health care economics, and strong communication skills.

If appointed to the Board, I anticipate sharing this type of perspective with Maryland's pharmacists to help ensure their value to the health care delivery system. ℞

Joseph A. DeMino

410 Midsummer Drive
Gaithersburg, MD 20878

Graduated
1984, University of Maryland
Practice
Community/Chain

Public service, community interaction, and the desire to improve patient healthcare are the primary reasons I decided to pursue a career in pharmacy, following the footsteps of my father. I made this commitment during my undergraduate education at Mount Saint Mary's College in Emmitsburg, Maryland and subsequently completed my pharmacy degree at the University of Maryland at Baltimore. As a life-long resident of Maryland and an attendee of public schools through high school, I wish to serve the citizens of the state as a member of the Maryland State Board of Pharmacy. Board service is one opportunity for me to add value to my community, as compensation for the benefits I have enjoyed my entire life.

Rapid evolution in technologies, changes in pharmacy education and expanded practice of pharmacists in delivering patient healthcare are environmental challenges facing our profession. In the midst of these advances, I believe the mission of pharmacy is unchanged; to assist patients to make the best use of prescriptions to improve their health. Revised laws and regulations will benefit the public only to the extent that they satisfy the dual role of protecting the public and enabling the practicing pharmacist to deliver quality patient care.

My education, training, and experience over nearly 20 years have provided me with an expanded perspective regarding the provision of pharmacy services for the benefit of patients. In my present position as a pharmacy supervisor for 18 CVS Drugstores, I am intimately involved with pharmacy practice and the supervision of pharmacists on a daily basis. I have held previous positions as a pharmacist, pharmacy manager, store manager, and manager of pharmacy systems. I have also spent considerable time in the development and implementation of pharmacy computer systems and third-party management. And, prior to completing my pharmacy education, I worked as a store clerk and pharmacy technician during my summer and holiday vacations.

I am requesting your support for my candidacy on the basis of my strong desire and qualifications; and of equal importance, upon my personal commitment to exceptional community service. I am appealing to your professional desire to improve patient healthcare and I offer my time and dedication as repayment for your support. ℞

Board of Pharmacy Candidates: Seat #1

Wayne A. Dyke

900 Farmstead Road
Cockeysville, MD 21030

Graduated
1968, University of Maryland
Practice
Community/Chain

As health reform proceeds, the managed care concept continues to influence all professional practices and settings. Providers, payors, and regulators involved must make every effort to insure that the patient is not the "pawn," but the "reason" for the reform process especially as it applies to the delivery of pharmacy services.

If appointed to the Board, I will maintain a perspective that will acknowledge the needs of the patient and the needs of pharmacists to best serve their patients in the most practical manner possible. I have gained insight and sensitivity to these needs from 28 years of community retail practice with both Read's and Rite Aid drug chains serving as a staff pharmacist, pharmacy manager, district supervisor, director of professional placement, and pharmacy development manager. I have also had the good fortune to serve with, and learn from, colleagues in various practice settings other than retail while serving with them on the University of Maryland School of Pharmacy Educational Advisory Board, as a member of the Maryland Poison Council, and as a member of the Maryland Pharmacists Association. I have also benefitted from association with professional colleagues in the Maryland Chain Drug Stores Association. Elected Member-at-Large of the Dulaney High School Sports Boosters is one of my civic responsibilities.

The Board needs to continue to be the formal link between the profession and the patient and to actively recommend, formulate and maintain the standards that will preserve the public trust that our profession has enjoyed in the State of Maryland for so many years thanks to a job well done by our Board. I consider nomination to the Board of Pharmacy an honor and privilege, and will accept without hesitations the responsibilities with your approval and appointment. ℞

Sheldon B. Pelovitz

2734 Woodridge Court
West Friendship, MD 21794

Graduated
1973, University of Maryland
Practice
Community/Chain

"Challenge: a summons that is often threatening, provocative, stimulating, or inciting." Webster's 10th edition

The Maryland State Board of Pharmacy continues to face its share of challenges, as defined above. It takes a lot of dedicated effort on the part of Board members to face these challenges. I am up to that challenge, I welcome it, and see it as a way to serve my chosen profession and to make a positive contribution to the future of pharmacy.

It is important to be constantly looking for new tools and/or methods to enable us to provide the highest level of pharmaceutical care and services to our patients and other health care providers. Since 1979, as a member of management for a local retail chain, I have been actively exploring applications of new technologies to advance the practice of pharmacy. I welcome the opportunity and the challenge of bringing my insights and experience in these areas to our Board.

It is truly an honor to be nominated to serve on our Board. As a Board member, I will work diligently to represent all pharmacists in the state, without regard to the different settings in which we practice. In addition, I will promote regulations that will protect the citizens of Maryland as well as the profession of pharmacy. I thank you for your support, I ask for your vote. ℞

Board of Pharmacy Candidates: Seat #2

Richard D. Baylis
1700 Sherwood Avenue
Baltimore, MD 21210

Graduated
1961, Albany College of Pharmacy
Practice
Institutional/Long-Term Care

We hear so much about the twenty-first century and we are still only five years away from it! But, medical care is changing more rapidly than it has in the first 2000 years. We are mapping the human genome and for many other living organisms. And as medical care changes, so does our profession.

Even the Board of Pharmacy recognizes that change is occurring by beginning the overhaul of the entire Maryland Pharmacy Practice. The Board must move ahead with this project quickly without sacrificing quality and thought. It cannot wait twenty-five years as it has in promulgating the inpatient institutional and the long term care regulations!

What can I bring to the Board of Pharmacy? In my career, I have had the unique credentials of having been a store owner, chain store pharmacist and manager, hospital pharmacist, long term care pharmacist, consultant pharmacist, DUR director, and have worked in national, state, and local pharmacy associations. I have made presentations at the annual meetings of most of the national pharmacy associations, plus the American Society of Law, Medicine, and Ethics, The Food Drug Law Association, Drug Information Association, National Association of Medicaid Pharmacy Directors, South East Conference of Drug Abuse, the French and Dutch Pharmacy Associations and conferred with medical care persons in Russia, Finland, Estonia, China, Japan, England, Canada and many other countries. I believe that my diverse background better enables me to bring a balanced perspective to the Board of Pharmacy.

The Board needs to be more assertive and attentive to practitioners inquiries. Written responses to questions of law, regulations, and policy should be timely and meaningful. The profession looks to the Board for guidance; as a Board member, I will insist that we accept that responsibility. License renewals should never be mailed late; as a Board member, I will insist that we accept that responsibility as well. We should see more visible cooperation between Drug Control and the Board. The agencies should complement each other and on the same "wavelength" when answering questions; as a Board member, I will work to bring these groups together.

I ask for your vote for a seat on the Maryland Board of Pharmacy and pledge to serve you and our profession with the utmost of my abilities and expertise. ℞

David B. Knauer
2930 Northwind Road
Baltimore, MD 21234

Graduated
1971, University of Maryland
Practice
Institutional/Hospital

Change through operations redesign is the central theme in today's healthcare environment. We are no longer surprised when we hear that change has recently occurred, or will soon occur, in a facility somewhere within our community. We have come to know this as the norm, not the exception.

Since change is inevitable, and will likely continue to bring on profound structural changes in healthcare, it will become necessary for governing boards to closely monitor the course and progress of these changes to assure quality and access to care. The Board must remain knowledgeable and focused on restructuring issues which will require program or policy development not only so that the profession flourishes, but also to ensure the highest quality patient care.

While I am a candidate for the "institutional" seat, I believe current changes in healthcare will ultimately affect all areas of pharmacy practice. I also believe that my extensive professional background will allow me to prepare and respond to these changes. My experience includes positions as an independent pharmacy manager, retail chain executive, hospital pharmacist and administrator. I am currently a Clinical Instructor for the University of Maryland School of Pharmacy and past faculty member of the Division of Continuing Education, Essex Community College. Professional affiliations include previous terms as Secretary, Board Member, and President of the Alumni Association, University of Maryland School of Pharmacy. Additionally, I have been a member of the Board of Directors of the Maryland Society of Health-System Pharmacists for the past five years and have the distinction of being the Society's first recipient of the prestigious Board of Directors Award. I am a present member of the American Society of Health-System Pharmacists as well as a life member of the University of Maryland Alumni Association.

By combining previous experiences with fresh perspectives, I believe I can successfully serve the profession and the public as a member of the Board of Pharmacy. My background, experience, and enthusiasm will allow me to become the conduit between the profession and the public to guarantee the communication and comprehension which is critical for the long term success of health care. ℞

Board of Pharmacy Candidates: Seat #2

Michael J. Orsini
1224 Athens Court
Bel Air, MD 21014

Graduated
1985, Temple University
Practice
Institutional/Hospital

It is a well recognized fact that health care in the United States is undergoing rapid changes, with managed care dominating the agenda. Whether you believe in managed care or not, the profession of pharmacy must be a part of these changes, or risk being left behind. The State Board of Pharmacy is important for seeing that pharmacists have a voice in these changes, not just as a regulatory group, but also as an advocate for the profession.

Although the public views pharmacists as trusted professionals, many decision makers in health care still view us simply as a supplier of a product (the drug). Yet we know that pharmacists do much more. There is no health profession today better equipped to deliver information regarding the cost-effective and safe use of medications than pharmacy, yet in day-to-day practice, pharmacists are often asked for their input *after* a problem has occurred. For this reason, pharmacists must be included with other professionals in the decisions that are shaping health care today.

I am a 1985 graduate of Temple University School of Pharmacy in Philadelphia. I have spent 11 years in hospital pharmacy, the last four as drug use evaluation coordinator and clinical pharmacist for managed care systems at the University of Maryland Medical System. Through my specialty practice I have gained extensive experience in medication use evaluations, adverse drug event prevention, formulary management, continuous quality improvement, outcomes research, and pharmacoeconomics. Furthermore, I have been a member of the Pharmacy and Therapeutics Committee during this time period. I am also a clinical instructor at the University of Maryland School of Pharmacy.

While my primary practice has been in hospital pharmacy, I have experience in retail and home health care pharmacy as well. I feel that my background in hospital pharmacy would bring a different perspective to the State Board. I welcome the opportunity to serve the profession. As a member of the State Board, I will work to see that pharmacy is included in important health care decisions, especially those that directly effect the profession and patient care. ℞

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Board of Pharmacy Candidates: Seat #1

Please select **up to three (3)** names from the following list of four chain pharmacy candidates by checking the box appearing beside their name. Your ballot will be disqualified if you vote for more than three names. You may vote for less than three names if you so choose.

☐ Stanton G. Ades
☐ Joseph A. DeMino
☐ Wayne A. Dyke
☐ Sheldon B. Pelovitz

Board of Pharmacy Candidates: Seat #2

Please select **only one (1)** name from the following list of three institutional pharmacy candidates by checking the box appearing beside their name. Your ballot will be disqualified if you vote for more than one name.

☐ Richard D. Baylis
☐ David B. Knauer
☐ Michael J. Orsini

When finished voting, turn this self-mailing ballot over and fold on the dotted lines. Return your ballot to MPhA no later than April 10, 1996. For questions, call MPhA at (800) 833-7587.

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At Issue

Jennifer Weiland, Pharmacy Student
UMAB School of Pharmacy

As the market continues to increase for nonprescription drugs (OTCs) -- a billion dollar plus industry -- one is forced to question whether or not patients are at risk in their endeavors to self medicate with these drugs.

Since 1972, more than 40 active ingredients have been switched from prescription to OTC status.[1] And more recently, a Department of Commerce report predicted that fifty more prescription drugs will undergo this change within a few years.[2] Moreover, it has been necessary for the Federal Drug Administration to establish an office to manage the new OTC applications.[3] It has been assumed that as manufacturers prepare to expand their OTC markets, patients will continue to boost sales as long as the drugs have been proven to be safe and effective and remain relatively inexpensive. Furthermore, there have been studies done which show that as many as 70% of consumers use OTCs to treat their illnesses.[4-6]

Associated with an expanded OTC market and increased sales is the essential need for more information and education on these drugs. For example, a Food and Drug Administration (FDA) study, (Hecht 1976), reported that 16% of 576 Bostonians did not read OTC labels although 75% agreed that it was important to do so.[7] Patients who might read the labels do not necessarily compehend all of the directions for use or comply with them. The warnings, the side effects, and the terminology may confuse them.

Also, patients probably are not aware of the adverse reactions or the interactions of OTCs used in combination with other OTCs and drugs such as alcohol, nicotine, and caffeine. This fear is not unfounded as demonstrated by the FDA Nonprescription Drugs Advisory Committee's recent rejection of several prescription drugs being switched to OTC status.[8] It is the argument of this article that patients are at risk in their attempts to self medicate with OTC products because the expansion of the market increases the potential for misuse, abuse, and misunderstanding.

It has been assumed that nonprescription drugs are legitimately safe if properly labeled and packaged, and if they are used according to the label and if attention is given to all warnings and potential side effects. According to law, labels must include symptoms the medication is designed to treat, warnings and side effects, and what instances a doctor's advice must be sought prior to use.[9]

The enormous amount of information displayed on these packages creates confusion on behalf of the patient. For example, a survey was conducted by Shands, Goff, and Goff (1980-1981) at the University of Southern Mississippi to assess perceptions, knowledge and related behavior concerning OTCs. Results showed that 20% of the students could not match "sodium restricted diet" with "not much salt." Sixty-one percent thought "not for prolonged use" meant for up to 8 days. And 50% would have waited 1-4 weeks for an OTC to alleviate a cough before calling a doctor.[10] The behavior of these students has proven that they are at risk to jeopardize their health and that more education and information on OTCs is in order.

Another problem associated with OTC use is the failure of patients to recognize OTC products as drugs without the prescription label. A 1994 case report presented by Davies, Fattah, and Clee showed that self medication is not often reported by patients to physicians because they do not consider OTCs to be drugs. Such was the case of a 69 year old man who sustained a head injury, recovered, and then began to experience forgetfulness and deteriorating concentration. He sought help, and his self medication, a continuous intake of calcium carbonate tablets along with 3 pints of milk a day, was initially undisclosed to his doctor upon hospital admission. The abnormal serum calcium levels which were responsible for his condition could have been detected much earlier and many tests could have been avoided had this piece of information been initially disclosed.[11] However, the patient did not consider antacid tablets drugs. A hospital admission like this, in addition to misuse and abuse of OTC products, can be avoided with improved education and counseling. The physician and the pharmacist should be more thorough in checking the patient's profile and previous history, and in questioning them about vitamins and their diets.

It is important to note that children are also at risk in their inability to recognize OTCs as drugs because many of the tablets and capsules look like candy and have attractive colors. This can lead to unintentional ingestion exposures, reported in 1990 to have reached 73,680 exposures in preschool children.[12] Furthermore, the American Association of Poison Control Centers reported that OTC cold medications were a frequent cause of unintentional ingestion in preschool children.[13-14] Again, these accidental ingestions can be avoided with increased education and counseling on OTCs.

The efficacy of an OTC constitutes another risk factor in the patient who attempts self medication. Most patients trust the OTC to be effective and never question this given that the OTC has passed through the FDA's stringent guidelines in order to be marketable. However, a critical review of clinical trials on OTC cold medications proved differently. The review, conducted across a 41 year time span, was completed by Smith and Feldman. They concluded that there was a lack of sufficient evidence demonstrating the effectiveness of OTC cold medications in children, and many OTC combinations were shown to alleviate symptoms in adolescents and adults.[15] It can be inferred from this information that the average adolescent or adult probably would not know, without the advice of a physician or pharmacist, what combination of OTCs would be effective in reducing their symptoms. In regards to children, one must question how these ineffective cold products reached the market in the first place. More studies need to be done and patients need to be educated and counseled in order to prevent ineffective products from reaching children.

pecial attention should be given to the case of a patient who lacks medical insurance because they are more prone to delay necessary treatment by using OTCs -- cheap, self help cures. A study was conducted by Stuart and Grana in 1990 to determine the effects of health insurance on medicine choices by the elderly. In their report, multivariate analysis confirmed that "the presence of insurance significantly increases the level of prescription use and significantly reduces the level of OTC use."[16] This suggests that OTC usage would increase in patients without any insurance. Thus, Stuart and Grana determined that a strong positive relationship between problems suffered and the percentage treated with OTCs did exist, and that this was a very well pronounced effect in patients who had no Medicare.[17]

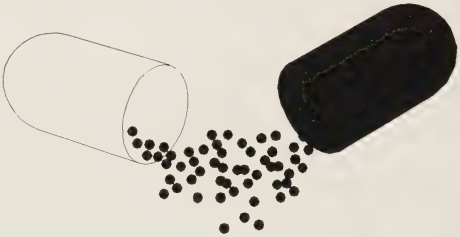
I recognize that health insurance plays an important role in a patient's decision to self medicate with OTCs. However, patients are trapped into a pitfall when they think that self medication with an OTC will be equally efficacious as an prescription. In addition, these patients are substituting OTCs for treatment that really may be necessary, and as a result, their condition may worsen. Also, the potential for abuse and misuse is heightened simultaneously with the need for health reform and education across all ages.

Some patients may feel well assured by the information received from their doctors and pharmacists regarding OTC use. In addition, they may feel that the choice of what OTC to use and the responsibility of one's health is ultimately theirs. However, this article has demonstrated several risk factors that the patient needs to be aware of in making those decisions. It has also been shown that more education and information regarding OTC use would benefit the patient greatly by helping to prevent misuse, abuse, and other drug related problems.

However, there still remain others who would challenge this argument. For example, the nonprescription drug manufacturers may respond that the FDA's review of OTCs ensures that they are safe, effective, properly labeled and packaged. Nevertheless, it must be considered that the FDA is not infallible and that this article has demonstrated that OTCs which are not effective have reached the market. Although the FDA requires that OTCs pass stringent guidelines, this does not mean that patients will read and understand labels, warnings, and side effects, use OTCs properly, or avoid health threatening combinations with other OTCs and legend drugs.

The patient's physician may have two different responses to the argument proposed in this paper. On one extreme level, the physician may think it is better for the patient to seek his/her assistance as opposed to OTC use, or he/she will not favor this or want to be flooded with an increased patient load. It was estimated in 1983 that an increased patient load would mean an increase in primary care practitioners -- 91,000-147,000 at a cost of nearly $10 billion.[18] Today, that would cost the country an even greater amount of money. A way to circumvent this would be for patients and health professionals to recognize that pharmacy is undergoing a revolution to a more patient-oriented practice.

Part of the new mission for pharmacists can be summarized in Principle I of APhA's "White Paper on the Role of the Pharmacist in Comprehensive Medication Use Management", which states: "Pharmacists must acknowledge the existence of and accept responsibility for preventing misuse and suboptimal therapeutics associated with prescription and nonprescription medications."[19] A proposed means to execute this mission would be for pharmacists to provide much needed patient education and counseling on OTCs called for in this article.

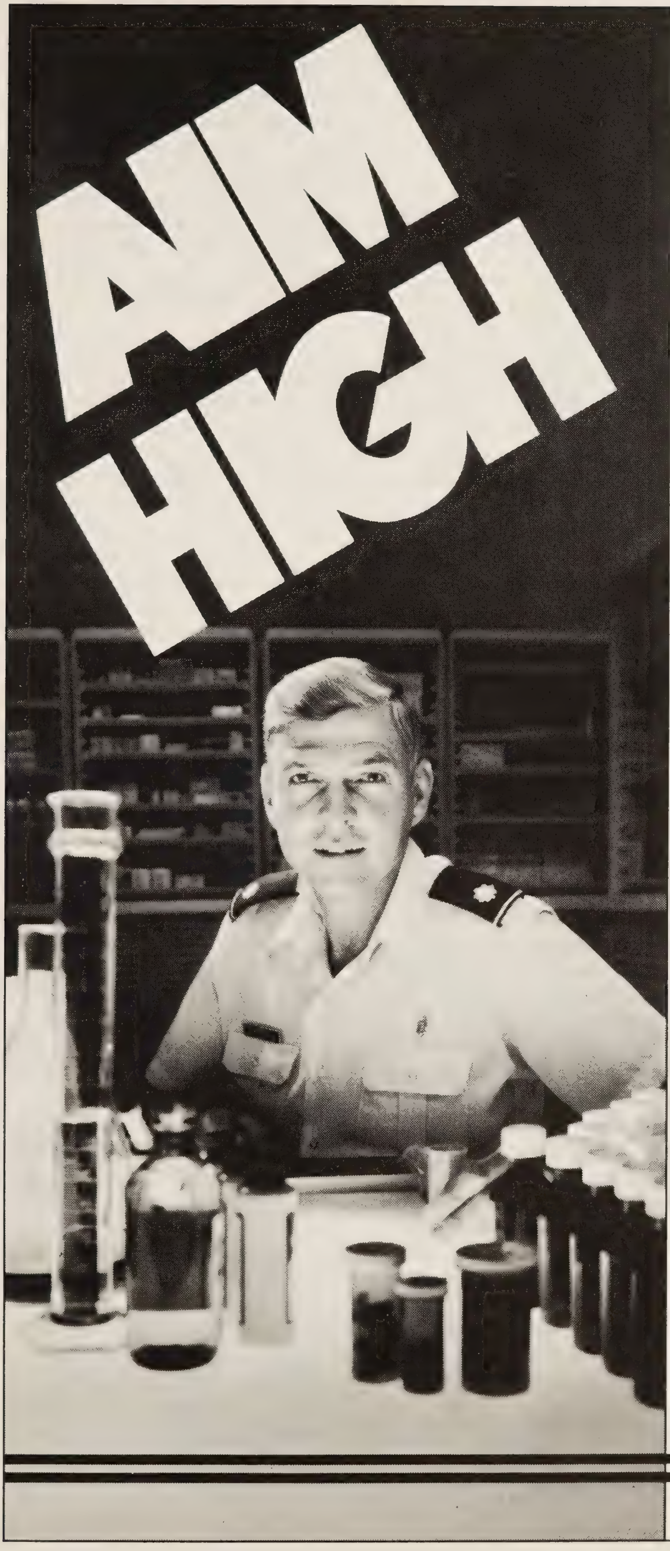


A study conducted by Nichol, *et al.* has demonstrated the value of patient counseling on OTC purchasing decisions. The research assumed that a change in the patient's OTC purchase decision constituted evidence that the consultation was valuable to the patient.[20] Furthermore, results showed that approximately 40% of the patients changed their decisions after consultation.[21] This research suggests that counseling and education on OTCs is valuable and it works. Moreover, the factors described in this article that put patients at risk when attempting to self medicate with OTCs could potentially and successfully be reduced by pharmacist interventions.

The pharmacist should be active and assist patients in reading OTC labels, explaining side effects and warnings, and in answering questions or concerns patients might have in terms they understand. Thus, a patient who comprehends what is written on the package of the drug will not jeopardize his/her health through misuse and abuse.

Secondly, the pharmacist can help patients to understand that OTCs are drugs by counseling, checking their profiles thoroughly, questioning patients on lifestyles, and distributing information. Again, the potential for misuse and abuse will be decreased. Lastly, the pharmacist needs to point out to patients that OTCs are not necessarily equivalent to prescriptions in efficacy and serious illnesses might require prescription strength medication and a physician's assistance. This would help patients to prevent delaying necessary treatment as a result of OTC usage. Because the value of patient counseling has been demonstrated, it can be concluded that future attempts by the patient to self medicate with OTCs can be made safer. **MP**

This article is one in a series of investigative opinion papers written by pharmacy students at the University of Maryland School of Pharmacy. References for this article are available upon request by calling the editorial offices at (800) 833-7587.



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AIR FORCE

David B. Brushwood, R.Ph., J.D.

The Court of Appeals of Michigan has recently reversed a verdict in favor of a pharmacy, ruling that the trial court incorrectly dismissed the pharmacy from the case based on an erroneous conclusion that the pharmacy owed no duty to the patient to screen for drug-drug interactions.

The facts of the case disclose that the patient had been prescribed the drug Parnate after an attempted suicide in October, 1989. The patient knew that Parnate was a monoamine oxidase inhibitor, and that it could cause severe complications if taken with foods or with other medications. On February 26, 1992, the patient developed a cold and went to a physician for treatment. The physician's notes indicted that the patient told him that he was currently using Parnate. The physician prescribed Ceftin and Tavist-D.

The patient went to the defendant pharmacy, where he normally went to have his prescriptions for Parnate filled. He had his prescription for Parnate refilled at this pharmacy eleven days earlier. The pharmacist who filled the prescriptions for Ceftin and Tavist-D testified at her deposition that she was not aware that the patient was taking Parnate when she filled the new prescriptions. According to the pharmacist, due to the pharmacy's computer system, a drug interaction *was* detected between Parnate and Tavist-D. The pharmacist said that she did not personally see the interaction on the computer, probably because a technician overrode it. The pharmacist was sure that the computer detected the interaction because the letter "I" appeared next to the price on the prescription label. The pharmacist testified that had she known the patient was using Parnate, she would not have filled the prescription for Tavist-D.

The patient used the prescribed medication according to the directions. He later complained to his wife that he was not feeling well. The patient and his wife referred to patient information literature for Parnate, and concluded that he was suffering from a hypertensive crisis. The patient was taken to a hospital where he suffered a stroke as a result of ingesting Parnate in combination with Tavist-D. On July 16, 1992, the patient committed suicide, leaving a note claiming that, among other things, the stroke was too much for him.

The patient's wife filed suit against the prescriber of the Tavist-D and against the pharmacy that dispensed the medications. The trial court dismissed the case against the pharmacy, ruling that liability was entirely with the physician, and that there was no duty on the part of the pharmacy.

On appeal, the court first addressed the plaintiff's contention that the pharmacy owed a duty to the patient because of its implementation and use of a computerized system to detect problems with drug therapy.

The defendant relied heavily on prior case law from Michigan, which had held that pharmacists are not generally liable when they process a prescription order correctly. The court acknowledged that prior cases had been decided under this rationale. However, the court noted also a section of a prior case, in which the court had specifically reserved consideration of the scope of

liability of a pharmacist where the pharmacist fills two incompatible prescriptions.

The court observed that the defendant had advertised that its computer system was designed in part to detect harmful drug interactions.

The court quoted from one of the defendant's advertisements as follows: "Do you know what happens when you bring your prescription to Arbor Drugs? First, it's checked for insurance coverage and screened for possible drug interactions and therapeutic duplication. Then your prescription is filled and labeled. That's done very carefully, by your Arbor pharmacist. The bottom line? Your prescription is not just filled quickly, it's filled safely. Only at the Arbor Pharmacies. You can't get any better."

The court concluded that the pharmacy had voluntarily assumed a duty to utilize its computer technology with due care through its advertising. Thus, the trial court had erred in concluding that the pharmacy owed no duty to the patient in this case, and judgment for the pharmacy was reversed.

There are several very important issues raised by this case. First, pharmacists must make sure that they adequately supervise technicians. To override a computer message that indicates two drugs interact with each other is a dangerous practice. This is an action that should be taken only with the knowledge of a pharmacist, who can recognize significant interactions and distinguish them from insignificant interactions. A computer that is so sensitive that it detects unimportant interactions and "cries wolf" frequently will be ignored when an important message is provided, and the computer needs to be adjusted so as to avoid the problem of unnecessary prompts.

Second, this case stands for the principle that pharmacies must actually provide the services they advertise to the public. It is unclear from the report in.this case whether the court would have held that the pharmacy had a duty, even if the advertising had not been as explicit as it was. The plaintiff based her case on the advertising, and that was the basis of the court's ruling. When one accepts the financial rewards of a successful pharmacy practice based on the promise of providing quality service to the public, one must also accept responsibility when things do not go well because promises have not been met.

One final point. Perhaps it is obvious. Had the pharmacist spoken with the patient for any length of time, the potential problem of the drug-drug interaction would likely have been disclosed, and the harm to the patient would not have occurred. Patient counseling is an effective liability limitation strategy. **MP**

Based on: Baker v Arbor Drugs, Inc., 1996 Mich.App. LEXIS 16 (January 16, 1996). Copyright 1996 David B. Brushwood. All Rights Reserved. Reprinted from *Dickinson's Pharmacy*, February, 1996.

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Continuing Education

Patient Counseling

Lice Infestations and Treatment with OTC Pediculicide Products

Thomas A. Gossel, R.Ph., Ph.D., Dean
Ohio Northern University

J. Richard Wuest, R.Ph., Pharm.D.
Professor of Pharmacy Practice, University of Cincinnati

A professional development program made possible by
an educational grant from **SEARLE.**

Head lice is one of the most common medical problems of children in the U.S., occurring in up to three percent of grade school children. Some officials claim that lice infestation is at near-epidemic proportions.

This lesson discusses head and pubic lice infestations. It illustrates how they are contracted, treated and controlled. It differentiates between the major OTC treatment product ingredients, and presents specific information for prevention of infestation that can be conveyed to victims or their family members.

A Primer on Lice

Lice are blood sucking insects. There are three varieties that infest humans: Pediculus humanus capitus (head louse), Phthirus pubis (public or crab louse), and Pediculus humanus corporis (body louse, also referred to as "cooties"). Body lice inhabit the seams of clothing and crawl upon their human victims only to feed. Infestations of body lice are not common in the U.S. and, therefore, are not discussed further in this lesson.

An infestation of lice is termed pediculosis. Since lice live on the body's surface, they are ectoparasites. A pediculicide is an agent that kills lice.

The precise incidence of lice infestation is not know, since the reporting of pediculosis outbreaks is not mandatory. It is estimated that more than 10 million cases occur annually in the U.S. The number of cases is increasing each year. Head lice are the usual cause of most lice epidemics. The retail market for lice treatment products is estimated to exceed $100 million.

Outbreaks of head lice traditionally occur in significant numbers in August, and increase greatly when schools reopen in September. They are reported at all grade levels in schools and institutions and in other communal living situations. The number of cases peaks in elementary school, and decreases as children grow older.

Head lice are most commonly spread by direct contact with the head of an infested person. They are spread indirectly from wearing clothing hung close to infested apparel in school coat rooms. They are also spread by sharing combs and brushes used by children with lice infestations. Bed linens and head rests on chair and couch backs are other sources of contact. Hair length is not an important criterion. Head lice occurs more frequently in females.

There is no significant difference in incidence among various socio-economic classes. Personal hygiene is not an important contributing factor.

Pubic lice differ from head lice in several important ways. Pubic lice are usually contracted by adults, affecting males and females at about equal rates. Although sexual intimacy is the most common means for acquiring them, they may also be transmitted from objects such as toilet seats, shared bedding, clothing and towels.

Differentiating Between Head and Pubic Lice

Head and public lice both appear on the hair and skin as tiny yellow brown to dark gray spots, measuring approximately 1 to 4 mm long. Neither's physical features can be distinguished by the unaided eye. They can be differentiated readily by viewing with a strong magnifying glass in good lighting.

Pubic lice are distinctly different from head lice. The site of infestation is the first consideration when attempting to distinguish between the two. Pubic lice infestations are normally found only around the genitalia and perianal areas. Head lice are found most commonly on the nape of the neck or behind the ears. They rarely leave the scalp area.

Head lice are elongated flat insects with short legs and claws. This cylindrical shape enables them to move freely among dense hair growth.

Pubic lice are shorter, broader and more rounded (hence their designation "crab" lice). They do not usually move far from the area of original infestation. Both forms are wingless, and neither jumps.

Their ability to cling to hair shafts is a distinguishing feature. The claw grasp of pubic lice matches the diameter of pubic hair. The claw grasp of head lice matches the diameter of scalp hair. This is one reason why the insects are fairly well restricted to their respective sites. It is difficult for either variety of lice to hold onto other hair.

Lice eggs (nits) are small globoid (i.e., shaped lice a chicken egg) or oval protrusions measuring about 0.5 mm that are bonded firmly onto the hair shaft by a sticky secretion from the female insect. This substance is strong enough so that nits will not be dislodged from the hair by ordinary washing.

Attempting to remove them causes the nits to fracture. Nits appear as yellow or white spots that are attached to hair shafts, touching or close to the skin.

Nits hatch within seven to 10 days into nymphs that must feed upon a human host within 24 hours to survive. These will molt three times within the following two weeks, transforming into mature adults. Following mating, adult male lice die quickly. Female lice will produce 250 to 300 eggs over their 35-day life span.

Lice are equipped with mouthparts adapted for piercing and sucking so that they may feed on the victim's blood. The insects' saliva contains an anticoagulant that is introduced under the skin of the infested host during feeding. This enables them to enjoy uninterrupted feeding of freely flowing blood. They may remain attached by their mouthparts to the same site for several days as they continue to feed. Head lice become engorged with blood; pubic lice seldom do. When engorged with blood, head lice may appear reddish.

An erthematous papule (small, reddish, raised and hard area) may begin to appear within hours of a bite. The bite area may also show a hemorrhagic component, caused by the anticoagulant injected at the time of biting. These papules may itch insatiably and, as a result of vigorous scratching, secondary bacterial infection may follow. A pustular eczema (dermatitis) may develop later.

Treatment of Lice Infestations

Treatment is based on achieving two goals: killing the insects and their nits, and controlling symptoms of infestation. Itching is the cardinal symptom and may be unrelenting. Secondary infection is the other concern.

Itching occurs in response to histamine and other inflammatory substances released in response to the insect's bite. It may persist for a week or longer, even after the causative organisms have

Representative Pediculicide Shampoos and Rinses

Ingredient	Trade Name
Permethrin	Nix Liquid Cream Rinse
Pyrethrum Extract 0.33% & Piperonyl Butoxide 4%	A-200 Pediculicide Shampoo Pronto Lice Killing Shampoo
Pyrethrum Extract 0.33% & Piperonyl Butoxide 3%	Lice-Enz Foam Shampoo RID Lice Killing Shampoo

Table One

been eradicated. Following removal of the insect, sufficient time is required for the host's body to eliminate these irritating substances, and for localized inflammation to subside.

An OTC antipruritic cream containing an antihistamine, local anesthetic or hydrocortisone may be applied topically and is usually sufficient to control the itching. Severe itching may require stronger therapy, or use of systemic antipruritic medication. Because of the persistent itching, it is common for patients to apply a pediculicide product repeatedly. This subjects the patient to increased risk of adverse effects from the pediculicide, including excessive drying of the skin which, in turn, can incite further itching.

Secondary bacterial infection is a rare occurrence. It includes impetigo and furunculosis (appearance of boils), appearing commonly at the nape of the neck and upper portion of the back. When infection is rampant, the victim's general health suffers.

Treatment includes application of an appropriate topical product such as triple antibiotic cream or ointment. When an infection fails to heal within seven days, or worsens, a physician should be consulted. Treatment may require more aggressive therapy such as a systemic antibiotic.

OTC Pediculicides

Pyrethrum Extract. Pyrethrum extract (0.17 to 0.33 percent) in combination with piperonyl butoxide (2 to 4 percent) is safe and effective for OTC use in controlling head and pubic lice. Pyrethrum extract (formerly termed pyrethrins) is a rapidly acting insecticide that kills insects by disrupting ion transport mechanisms at their nerve membranes. This mechanism correlates clinically to a massive systemic overdose of a local anesthetic with its toxic consequences. Affected insects experience convulsions, paralysis, and death.

Piperonyl butoxide is not insecticidal. It is included in pyrethrum extract mixtures because it potentiates the insecticide's action. It suppresses the insect's oxidative degradation mechanisms, thereby inhibiting their ability to detoxify the insecticide. Piperonyl butoxide is, therefore, synergistic with pyrethrum extract. The contact time with pyrethrum extract is prolonged, and insect kill rate increased.

Most reports of clinical toxicity with products containing pyrethrum extract and piperonyl butoxide relate to solvents in the preparation.

Commercial preparations of Pyrethrum extract consist of a mixture of substances obtained from flowers of the plant, Chrysanthemum cinerariaefolium. This mixture contains substances identified chemically as esters of chrysanthemic acid and pyrethric acid, and three alcohols, pyrethrolone, cinerolone, and jasmolone.

OTC products (Table One) containing pyrethrum extract are safe for human use. The product should be applied to dry hair and scalp and allowed to remain for 10 minutes before washing with soap and water or regular shampoo. The application may be repeated in seven to 10 days to kill newly hatched eggs.

Neither the insecticide nor piperonyl butoxide are absorbed extensively following topical application. The small quantity that may enter the blood is metabolized rapidly. The estimated fatal oral dose of pyrethrum extract for humans is 0.7g/kg, and for piperonyl butoxide, 11g/kg.

Adverse effects following application of a product containing pyrethrum extract and piperonyl butoxide are uncommon. Contact dermatitis is the most frequently reported affliction. Since pyrethrum extract is obtained from natural plant origin, allergic rhinitis and asthma attacks may be precipitated in susceptible individuals. Cutaneous irritation normally disappears within several minutes. Inhaled pyrethrum extract may cause nausea and vomiting, and on rare occasion, muscle paralysis and death.

Reports of the potential for pyrethrum extract-induced allergic response are conflicting. There is no standardized procedure for extracting the insecticide from its natural sources. The allergenic component(s), therefore, may or may not be present in any batch. Nevertheless, the chance of an allergic reaction in a susceptible person is sufficient to warrant the warning statement, "Use with caution on persons allergic to ragweed," on all preparations containing pyrethrum extract. Purchasers of these products should be made aware of this warning.

Most reports of clinical toxicity with products containing pyrethrum extract and Piperonyl butoxide relate to solvents, typically petroleum distillates in the preparation. Ingestion of as little as one teaspoonful of a product by a child could be fatal.

Pyrethrum extract is indicated for treatment of head and pubic lice infestations. The products are also ovicidal. One product, Pronto, is being promoted as containing a new formula that has been shown to be 100 percent effective in killing lice and nits, and has no residual pesticide action.

Permethrin. Permethrin is a synthetic pyrethroid that is believed to act by the same mechanism of action as pyrethrum extract. The rinse should be applied in the same manner as pyrethrum extract shampoos. It has a low toxicity in mammals since it is absorbed poorly, and inactivated rapidly by ester hydrolysis. It is contraindicated in persons hypersensitive to chrysanthemums, pyrethrum extract or synthetic pyrethroid.

Permethrin is retained in hair shafts for up to 14 days regardless of the nature of shampoos, or other drugs or cosmetics that may be applied to the hair. One treatment is both insecticidal and ovicidal, and is reported to provide protection from reinfestation for up to 14 days. Permethrin is indicated for treatment of head lice only.

Adjunctive Measures to Control Lice Infestations

Washable Clothing: machine wash in hot water, dry in the hot cycle for at least 20 minutes, and press with a hot iron.

Non-washable Clothing: dry-clean or seal in a plastic bag for three weeks.

Personal Grooming Articles: soak combs, brushes, etc, in hot water for five minutes, or in water containing an antiseptic or a pediculicide product for one to two hours.

Carpets and Stuffed Furniture: vacuum thoroughly or spray with an OTC aerosol product.

Table Two

Temporary itching, burning, stinging, numbness and pain have been reported following permethrin application, but these are rare. The product should not be used in infants because of the greater permeability of their skin, and reduced ability to metabolize it.

Some medical authorities have expressed concern over the use of synthetic pesticides such as permethrin. Because permethrin remains in hair shafts for prolonged periods of time, they feel that this exposes children to potential health hazards. They recommend that the pesticide obtained from natural sources be used as a logical alternative treatment because of its safety record established over decades of use.

OTC pediculicide products may cause irritation to the eyes and mucous membranes. Products must be labeled to warn against their use near these areas. Lice infestations on eyebrows and eyelids may be treated safely by applying a thin layer of petrolatum and rubbing it in well. It kills lice, probably by mechanically blocking the insects' respiration.

Adjunctive Treatment

OTC pediculicide products do not readily dissolve the cement substance that holds nits onto hair shafts, or dislodge them from their point of attachment. After application of the product, dead lice and nits can be removed manually with a fine-toothed (or special precision) comb or be picked off, one by one, using fingers or tweezers. Back-combing with a fine-tooth comb is the most effective maneuver, because of the angle of the attached nit in relation to the hair shaft. A solution of vinegar diluted one-half with water, or rubbing alcohol used full strength or diluted, is reported to be useful in helping dissolve the cement substance. After several minutes the hair should be shampooed, dried and brushed. The nits can then be removed more easily.

The social stigma that accompanies lice infestation has created a demand for a number of home remedies and self-treatment regimens. For example, it has been stated that the area can be heated with a hair drier until the skin tingles, or soaked in hot (but not scalding) water for three minutes. Both procedures kill some lice and nits. But these measures can be uncomfortable and damaging to the skin. And they are not likely to be effective for eradicating all insects and eggs.

Shaving the area is an effective means to remove all insects and their nits. But routine shaving is no longer advocated since pediculicidess are effective when used properly.

Advising Patients on Lice Infestations and Treatment

The affected person should be observed closely for the presence of lice and nits eight to ten days after initial drug application. Individuals with lice or nits remaining after two treatments should be evaluated by a physician to determine the source of infestation or reason for treatment failure.

Itching can persist for weeks beyond eradication of the insects and may be controlled with antipruritic products. Patients should be advised to not confuse hair spray globules, hair casts, dandruff or other extraneous debris with nits. The former are easily dislodged and brushed away. Nits remain firmly attached.

Pediculicide should not be applied to damaged skin, mucous membranes, eyelids or eyelashes.

CE Info

Goals

The goals of this lesson are to describe the etiology, prevention and treatment of lice infestations with OTC pediculicide.

Objectives

At the conclusion of this lesson, participants should be able to:

1. identify the etiology and prognosis of lice infestations;
2. differentiate between OTC pediculicide product ingredients;
3. select from a list the pharmacologic and toxicologic properties of OTC pediculicide product ingredients;
4. identify adjunctive measures that will maximize treatment of head lice infestations; and,
5. demonstrate the ability to counsel patients on the causes, prevention and treatment of head lice infestations.

CE Quiz

MPhA members can receive one contact hour of ACPE approved continuing education by completing and returning the CE Quiz that appears on page 38 of this issue.

This program has been approved for one credit hour (0.1 CEU's) of ACPE approved continuing education. The Maryland Continuing Education Coordinating Council is an approved provider for continuing education programs for pharmacists by the American Council on Pharmaceutical Education. **ACPE #144-999-96-001-H04.**

When one individual in a family has lice, other family members should also received treatment unless it is absolutely certain that they have not been exposed. All personal items, and areas of the home which may have been contaminated, must be decontaminated if treatment is to be completely effective.

Sheets, clothing and other washable items should be machine washed with hot water, then dried on the hot cycle for 20 minutes or ironed. Heat is lethal to lice and nits. Nits are killed by exposure at 135F for five minutes, or 30 minutes exposure to 120F. Adult lice are killed at slightly lower temperatures. Alternatively, the items can be dry cleaned, or stored in tightly closed plastic bags for about three weeks. This should be an adequate interval for all nits to hatch into nymphs. Without a food source, they will die shortly.

Combs and brushes should be soaked in hot water for five minutes, or in water containing an antiseptic or a pediculicide shampoo for one to two hours. Carpets and stuffed furniture should be vacuumed thoroughly, or sprayed with one of the commercially available aerosol products for that purpose. Vacuuming is equally as effective as sprays. Household pets do not become infested with human lice. It is, therefore, not necessary to treat them. Table 2 summarizes adjunctive measures for controlling lice infestations. **MP**

Continuing Education Quiz

March/April 1996 -- Lice Treatments

This month's questions are taken from the article on lice treatments that appears in this issue. Circle your answers to the following questions and mail the entire page to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. There is **no charge** for this quiz for MPhA members (non-members $5.00). The completed quiz for this issue must be received by April 30, 1997. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly. **ACPE #144-999-96-001-H04**

Name ______________________________

Address ______________________________

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1. All of the following counseling statements are appropriate for the use of pediculicide shampoos *EXCEPT:*
   a. allow the product to remain on the area for 10 minutes before washing it out.
   b. apply the product daily for seven to 10 days to assure that all lice eggs are killed.
   c. Use a special precision comb to remove dead lice and eggs after application.
   d. all infested clothing, bed linen, etc. should be laundered in hot water or dry cleaned.

2. Which of the following groups are infested with head lice significantly more often?
   a. Males versus females.
   b. Persons with long hair versus short.
   c. Poor persons versus the wealthy.
   d. Children versus adults.

3. Of the following, the major differentiating factor between head lice and pubic lice is:
   a. the size of their claws
   b. the length of their legs
   c. their color.
   d. their wings.

4. Which of the following statements is true?
   a. Lice eggs are colored red to dark brown.
   b. Lice eggs adhere to hair shafts by a sticky secretion from the female.
   c. Lice eggs are bonded to the end of hair shafts away from the scalp.
   d. Lice eggs hatch within 24 hours of being laid.

5. Pyrethrum extract kills lice by:
   a. suppressing their oxidative degradation
   b. Causing a cholinergic surge.
   c. disrupting their ion transport mechanisms.
   d. preventing them from breathing.

6. All of the following counseling statements are appropriate for the use of permethrin rinse *EXCEPT:*
   a. saturate the scalp with the product and allow it to remain overnight.
   b. do not use the product on eyebrows.
   c. combs and brushes used in the hair should be soaked in hot water for five minutes after each use.
   d. infested clothing that cannot be laundered can be placed in a tightly sealed plastic bag for three weeks to kill lice and eggs.

7. Which of the following statements is true?
   a. Pubic lice are elongated flat insects.
   b. Pubic lice can only be transmitted by body contact.
   c. Pubic lice can be distinguished from head lice using a strong magnifying glass.
   d. Pubic lice occur much more often in males than females.

8. The life span of the female louse is approximately:
   a. 1 day.
   b. 1 week.
   c. 1 month.
   d. 1 year.

9. Piperonyl butoxide acts on lice by:
   a. suppressing their oxidative degradation.
   b. causing a cholinergic surge.
   c. disrupting their ion transport mechanisms.
   d. preventing them from breathing.

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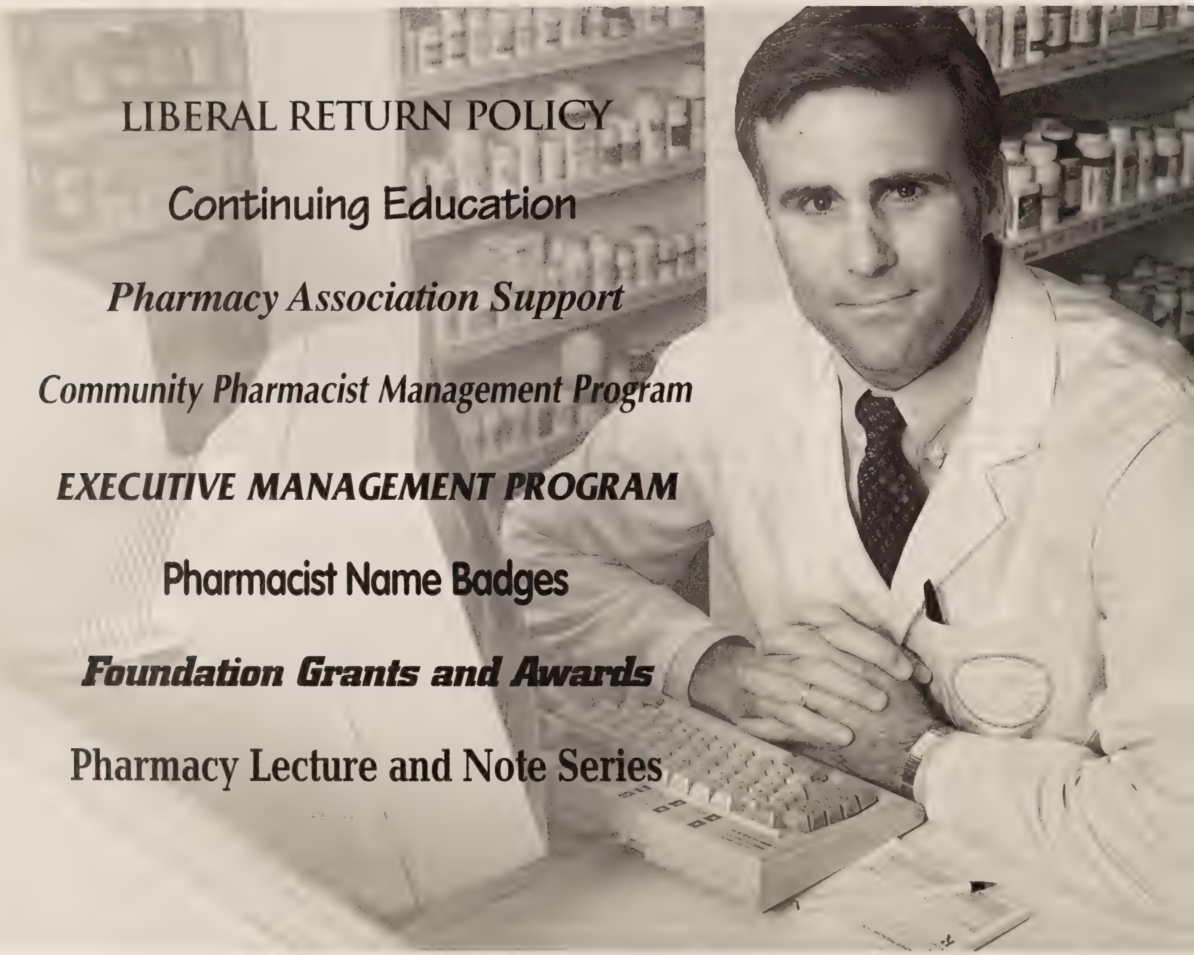

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4 President's Commentary

MPhA's Board of Trustees has developed a new set of strategic goals. MPhA President Jim Tristani unveils the first draft to our membership.

5 Pharmacy in Italy

Sabrina Maurer, MPhA's Association Management Extern, recently returned from a trip to Italy. Her observations about how they practice pharmacy present some unique observations that pharmacists in Maryland should consider.

9 Herbal Medicine - Part Three

Continuing from last month's issue, MPhA member William Skinner provides resources for pharmacists interested in expanding their services into herbal medicines.

18 Charting A New Course

The upcoming MPhA 114th Annual Convention promises to open your eyes to new opportunities in pharmacy, pharmaceutical care and MPhA. Use the registration form on page 22 to save your place at this exciting meeting.

24 Litigation Update

Attorney David Brushwood reviews a case that should be a lesson to all pharmacists: don't try to hide the facts.

25 At Issue: Pharmacist Prescribing

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President's Commentary
Thinking Ahead. Thinking Smart

For the past several months, I've used this forum to share with our members and non-members the progress of MPhA's strategic planning. Completing a plan for the future of the Association is one of the four goals that your Board of Trustees adopted for 1996 (the other three include increasing membership, taking a leadership role in the revision of the Pharmacy Practice Act, and deciding the future location of the organization's headquarters and the B. Olive Cole Museum.

After four months of long, exasperating, sometimes boring, sometimes exciting discussions at our monthly Board meetings, we gathered on February 24 for a nine-hour marathon session with management consultant Jim Cornelius. The purpose of this session was to take all of our talk, our needs, and our wants and then begin to put them into concrete, meaningful goals for MPhA. While still being refined, these goals meet the SMART standard we set for ourselves.

James Tristani, P.D.
1995-96 MPhA President

What are SMART goals? Basically, they have to meet five criteria. Here's the way it works:

Strategic
The goal meet MPhA's overall objective of improving pharmacy and the economic and professional opportunities for our members.

Measurable
Will we know if the goal is accomplished?

Attainable
A goal that can never, ever be accomplished is meaningless and not worth the effort.

Realistic
An unrealistic goal wastes precious and finite resources. If our goal is to stop the sun from coming up every morning, it's not SMART.

Timed
Everyone works better with a deadline. SMART goals have a specific end-point.

So, without further ado, here are the seven SMART goals that your Board of Trustees have developed:

- MPhA will obtain statutory authority for either independent or collaborative prescribing privileges by July 1, 1998.
- MPhA will have pharmacists to be paid for the provision of information and patient-oriented services beginning November 23, 1997.
  - Create standards of reimbursement for cognitive services apart from services of dispensing by July 1, 1997.
  - Implement a therapeutic module based series of continuing education programs that includes review of pathophysiology and disease treatment and a specific focus on pharmaceutical care and billing of cognitive services by December 31, 1996.
  - MPhA will negotiate agreements with companies who specialize in pharmacy practice re-engineering so that MPhA members can hire them at a discount, MPhA will get a percentage or per member utilization reimbursement no later than January 1, 1997.
- MPhA will conduct a public relations campaign -- radio, press and TV -- during October, November and December of every year that emphasizes that patients look for their pharmacist and pharmacy in any health care plan for which they sign up to help increase the public's recognition of their relationship with us.
- MPhA will establish a pharmacist hotline to answer membership questions by July 1, 1996.

When presented in rough form to our Mid-Year Meeting attendees, these goals brought a round of applause and praise. But, what do you think? I'd like to hear if you think our goals are SMART or dumb. Drop me a line care of MPhA or FAX me a note at (410) 727-2253. **MP**

Pharmacy in Italy

Sabrina L. Maurer,
MPhA Association Management Extern

Recently I had the opportunity to visit Italy and talk with Italian pharmacists.

Pharmacy is practiced quite differently in Italy beginning with pharmacy education. The pharmacy curriculum is a four year program with entry into the discipline immediately after high school. Pharmacy students in Italy do a six month internship in the months preceding graduation for four hours a day two or three times a week. They are not permitted to intern in hospitals or state-run pharmacies but must do their intern hours in privately owned pharmacies. There is a national pharmacy exam that all pharmacists must pass in order to practice and, as in the U.S., students take the exam within a few months of graduation from pharmacy school.

Italy has socialized medicine so pharmacy is quite heavily regulated by the government. There is a limit to the number of pharmacies in a particular area based on the number of inhabitants. In towns of under 12,500 people, there can only be one pharmacy for every 5000 inhabitants. In towns over 12,500 people there can be one pharmacy for every 4000. In either case, the distance between the pharmacies cannot be less than 540 yards.

To own a pharmacy, one must be a pharmacist who has practiced a minimum of three years in a rural setting or five years in an urban setting. New laws permit partnerships between non-pharmacists and pharmacists but the pharmacist must be the titleholder of the business. In addition to privately owned pharmacies, there are also ones owned by the local government.

Pharmacies are open Monday through Friday from 9 AM 1 PM and again from 4 PM to 8 PM as well as Saturday mornings. For the remainder of the weekend, nights, and state holidays, all pharmacies in a particular locality participate in a rotating schedule. Italian pharmacies also provide after hours service for prescription medications only. For safety reasons, most pharmacies have a box into which a prescription may be placed and from which the medication may be retrieved by the patient.

Prescription drugs come prepackaged so there is no counting by Italian pharmacists. If a patient only needs five tablets but they come in a package of 20, an entire box will be dispensed. These prescription products are not labeled, not even with the patient's name. However, Italian pharmacies are computerized. The computer prints out a sheet with the patient's name, the name of the physician, and the drug name and strength. Then the pharmacist transfers the bar coded sticker from the box of medication onto this sheet and the computer lists the price to the patient. Since this system is directly linked to the government, prescription prices are the same all over Italy. In order for the pharmacy to be reimbursed, a bill is submitted to the state once a month.

Inside a traditional Italian pharmacy. Note that most products are still maintained behind the counter in cabinets to encourage interaction with patients.

Prescription drugs are subsidized by the state and are based on three categories - A, B, and C. Category A consists of drugs for chronic conditions, such as hypertension and diabetes, and antibiotics. For Category A medications, the consumer pays about $1.50 per box. Category B contains most other drugs and the consumer pays 50% of the price established by the government. Individuals under six or over 65 years of age are excluded from this provision and pay $1.50. All drugs in Categories A and B require a physician's prescription to be dispensed. Drugs in Category C, such as vitamins and NSAIDS, are not covered. Category C is unique because it contains some drugs that require a physician's prescription and some that are *pharmacist* prescribed.

There are five divisions for controlled substances in Italy and dispensing records must be kept in the pharmacy for five years. Level one drugs, such as morphine and oxycodone, are prescribed on special yellow forms and kept in a locked cabinet in the pharmacy. Every pharmacy is also required to have methadone on the premises for the treatment of narcotic addiction and it is also a level one drug. Levels two and three correspond to the U.S. control one and have no medically accepted uses. Level four contains barbiturates and amphetamines and cannot be refilled. Level five contains benzodiazepines which can be refilled a maximum of five times in three months depending on the strength prescribed. Level five also contains anti-coagulants and anti-platelet drugs which may not be refilled.

Outside a local Italian pharmacy. Italian pharmacies are all identified by a green cross, a symbol used throughout Europe.

Non-prescription drugs are only sold in pharmacies and are kept behind the counter. These drugs are requested from the pharmacist who will question the patient about symptomatology and other medication use in order to recommend the best product. Other non-prescription items sold in the pharmacy include any product labeled as hypoallergenic, baby food, and other baby products. Most cosmetics, shampoos, soaps, toothpastes, antiperspirants, and mouthwashes cannot be purchased in pharmacies. However the cosmetics that are sold in pharmacies carry an expiration date.

Every pharmacy in Italy has a compounding area which contains equipment and drugs required by the state. There are two types of compounded drugs. The first type consists of those specifically written by a physician. The Italian Pharmacopeia furnishes recipes for the second type and these compounds are sometimes available in commercial preparations.

Homeopathy is somewhat popular in Italy and currently there are no laws governing homeopathic products. However they may only be sold in pharmacies.

As in the U.S., pharmacy in Italy is changing. The length of the pharmacy curriculum will soon be five years instead of four, the minimum distance between pharmacies will increase to over one mile, and young pharmacists who wish to purchase their own pharmacies will find the costs increasingly prohibitive. The pharmacists I spoke with showed an interest in the U.S. movement for pharmacist reimbursement for cognitive services and in the use of clinical pharmacists in hospital and long-term care settings. Clinical pharmacy services do not exist in Italy and these pharmacists think that there is a need for them.

I enjoyed learning about pharmacy practice in Italy and hope I have future opportunities to learn even more. I'm currently planning to complete a pharmacy practice residency in Philadelphia but once I've completed all my training I hope to obtain employment with a multi-national pharmaceutical firm so I can use my language skills along with my pharmacy skills in Italy. **MP**

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The author wishes to thank Dott. Alessandra Serafini for her time, patience, and for allowing me to photograph her at work. I would also like to thank Sig. Francesco DiPede for graciously driving me everywhere I needed to go and the Conte family (particularly Adriana) for hosting me and feeding me lots of wonderful Italian home cooking. *Grazie a tutti!*

Thank You!

As part of MPhA's partnership with the pharmaceutical industry, we have been able to provide you with continuing education booklets as part of our journal mailings. This issue's program is made possible by **Purdue Frederick** and its Account Executive Michael Heinzman. Thanks, Mike!

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Lawful Herbal Medicine

Part Three of a Three Part Series

William J. Skinner, R.Ph., J.D.

How does a pharmacist get ready for a future in lawful herbal pharmacy? How do you learn more about natural remedies, herbs, teas, immune stimulants known by American Indians, German herbal remedies, and good common sense first aid made from green medicine. This third and concluding part of our series on Herbal Medicine hopes to answer those questions. There are books, continuing education courses, field trips, and conventions to attend. This is like any other field of endeavor among people of interest and means.

One book to read is Mannfried Pahlow's book, *Healing Plants*,[13] in which this German pharmacist discusses self-treatment and supplementary phytomedicine treatments to be taken with the knowledge of the patient's physician for most of the common every day complaints. Pahlow gives time-tested recipes for teas, tea blends, tinctures, ointments, inhalations, compresses, and baths. This is also a must read for American pharmacists who provide pharmaceutical care. This book may be hard to get. I purchased my copy at the University of Illinois at Chicago Health Sciences Store, not an insignificant place to reach in this man's world. It is worth every cent of the $16.95 price, especially since it provides advice about consulting with the patient's physician on the use of these remedies. The chapters include: "Self--help with healing plants," "Nervousness and Sleep Disturbances," "Colds," "Bladder and Kidney Complaints," "Stomach and Intestinal Complaints," "Rheumatism and Gout," "Gallbladder and Liver Complaints," "Childhood Diseases," "Gynecological Complaints and Menopause," "Geriatric Complaints, " "Cardiac and Circulatory Disorders," "Minor Injuries, Skin Irritations," and a "Compendium of Medicinal Plants." Plus, it has photos of the plants, directions on how to prepare the remedies and administer them.

By now if you are thinking that this stuff is nuts and how could somebody such as the author put any credence in this area of bunk, think again? If you are thinking that, how would you know? Have you studied it? Are you an expert? I am not convinced that most pharmacists know very much about herbal medicine, especially if you have not had a course in pharmacognosy. But your education places you in a prime position to learn. And if you do, you can help the millions of patients who will be turning to this kind of medical solution because they think it is more natural, softer, gentler, more to the point, less expensive, and it is a way to get health care without the high cost and paper work of modern medicine.

During the past year I attended two meetings on Complementary and Alternative Medicine. The first was sponsored by FDA and NIH. The second was sponsored solely by NIH and concerned research methodologies. Not many pharmacists attended these seminars, probably less than a half dozen. At these meetings, a considerable amount of scientific information was given in lectures, and discussions and the meetings were somewhat quietly concluded. No big pronouncements resulted, there was not even news coverage inside the

Washington beltway, despite the enthusiasm displayed about potential new, inexpensive therapies. In time, there will be reports for sale under non-descript government titles and someday, there may be even an article in a professional journal or the newspaper about some of the reported discoveries that offer alternatives and complementary therapy to modern chemical bullet medicine. Here is a quick summary of the information I learned at these programs.

The NIH Office of Alternative Medicine in cooperation with the Food and Drug Administration held a three day conference in December 1994 on *Herbal Medicine: A Role in U. S. Health Care?* Five scientific panels presented information on: 1) What are botanicals and how are they currently used?; 2) How could we know that botanicals work?; 3) How could we know that these products are safe?; 4) How can we assure that botanical preparations will be of good quality? ; and 5) How do regulations affect the market place and impact the cost of health care? And there were several speakers on the "Economics of Botanicals" and "How could we best regulate botanicals?"

Toward the end of this conference, enough had been said that NIH medical scientists were asking if the larger group was ready for a consensus conference sponsored by NIH in which some agreement is reached on principles. And there seemed to be a readiness to have such a meeting of the minds. At this NIH/FDA conference one speaker estimated the German market in herbal medicines at $7 billion. The most used herbal drugs are Gingko biloba, valerian root, horsechestnut seed extract, saw palmetto berry extract, bitter-orange peel extract, garlic, Hawthorne leaf/flower extract, Ginseng root extract, Psyllium and Echinacea. In Europe the research trend is toward assessment of these phytomedicines; in the U.S., the FDA continues to require two adequate, well-controlled, double-blind studies and this and the expense are impediments to research. Whether the price tag of the research is $100 million or $359 million, companies will not invest if the results are not patentable.

FDA also wants herbal combination products reduced to active ingredients in order to do tests and quantify results. Somehow this requirement does not apply to interferon. In Europe, monographs for phytomedicines are being written, sometimes with the help of American scientists, while in the U.S., the public use of herb medicines is fought by the FDA with many regulatory tools, claiming it is all quackery. In Europe, if the herbal drugs are safe (such as the consumption of 100,000 tons a year without reports of illness and death) and the herb has some good effects, the product is permitted on the market.

Sources for Additional Information

Books

1. **Pharmacognosy**, 9th Ed. (1988) by Tyler, Brady and Robbers. Extensive explanation of plant and animal drugs. Hardcover, 519 pp. $65.00 from Williams & Wilkins, Philadelphia.
2. **The Honest Herbal** by Varo E. Tyler, 3rd Ed. (1993), Pharmaceutical Products Press at The Haworth Press, Inc., 10 Alice Street, Binghamton, NY 13904-1580. $19.95 retail. Organized alphabetically by herb name and contains a summary of modern scientific evidence of use or dangers. Tyler points out areas for more research and herbs to avoid because enough is already know to stay away.
3. **Herbs of Choice** by Varo E. Tyler, (1994), Pharmaceutical Products Press at The Haworth Press, Inc., 10 Alice Street, Binghamton, NY 13904-1580. $12.95 retail. This book expands on coverage of scientific literature, including European, about herbal medicines in categories of disease.
4. **Therapeutic Herbalism**, a 1992 correspondence course in notebook form by David Hoffman, 9304 Springhill Rod, Sebastopol, CA 95472. Shows practical use information by naturopaths and other herb healers.
5. **The Complete Book of Essential Oils & Aromatherapy** by Valerie Ann Worwood, New World Library, 58 Paul Dr., San Rafael, CA 94903 (1991), $16.50. A look at aromatherapy by a practitioner.
6. **The Healing Garden** by Sue Minter, Charles E. Tuttle Co., Inc., 77 Central St., Boston, MA 02109, 160 pp (1993), $18.71. Has sections on the healing arts, body physical, the senses and spiritual haven.
7. **A Bibliography on Herbs, Herbal Medicines, "Natural" Foods and Unconventional Medical Treatments**, by Theodora Andrews, (1982), Libraries Unlimited, Inc, P.O. Box 263, Littleton, CO 80160. A source book of other writings.
8. **The Healing Herbs**, by Michael Castleman. Rodale Press, 33 East Minor St., Emmaus, PA 18098 (1991), $26.95. Paperback which reviews herb medicines for 200 conditions and diseases. Each section has references to articles but no direct page footnotes.

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FDA has its heels dug in. FDA opposed the 1994 Dietary Supplement Health and Education Act to the very end, but Congress received overwhelming mail on the subject and passed the law without much legislative history, a point which guarantees the FDA continuing to battle against herb medicine use in the future. FDA has not proposed regulations a year after the Act was signed into law. Why does FDA act as it does? Maybe you heard the popular radio doctor Deane Edell ranting and raving about this law, which he claims gives companies permission to sell heroin if they labeled it as a "dietary supplement." He said the law prohibits FDA from doing anything about this kind of thing.

As pharmacists we know he was overlooking the Controlled Substances Act, and many other laws in his emotional attack against the dietary supplement law. Obviously, Dr. Edell is not aware that herbal medicine is used by most of the world or that European research scientifically supports its use in many instances. His intemperate outburst probably represents the level of knowledge of many U.S. health care providers.

The World Health Organization started an effort in 1992 to help countries use the best medicine they can use, especially indigenous medicines made of plants. In Australia the "Therapeutic Goods Act of 1990" was passed. In Canada, herb medicines are regulated as foods, plus as folklore medicine. In France, 205 herbs are recognized and in Germany 324 herbs are permitted to be sold, while 58 are not approved for sale. The rest of the world is passing the U.S. in this area of health care.

At the NIH research methodologies conference held in April, 1995, plant medicines were only a small part of the discussion by world-wide group of medical scientists and practitioners. Papers on studies of their use in migraine headaches and cancer were reviewed. Suffice it to say that a great deal of positive good in the treatment of individual illnesses can come from alternative therapies, including plant medicines. There remains healthy skepticism about pseudo-science, the placebo effect, and the effects of many herbal medicines, but there are definite and strange effects that need further study to confirm positive as well as negative results. The attitude at this meeting was more open, partly because NIH was funding many of the alternative medicine studies. But the basic emphasis was that some herbal and other unconventional therapies work and we do not yet understand why, so don't knock them if we do not know the truth.

Another program I attended this past summer was held at Purdue University's School of Horticulture. This was a 10-day seminar in June, 1995, on the subject of "Aromatic and Medicinal Plants," as a part of its New Crops series. As the only pharmacist in attendance from the United States, I found this course a fantastic source of information, and of great value in understanding the herbal medicine field. The Purdue faculty was headed by James E. Simon, Ph.D., and a number of horticulturists who was supported by a number of other faculty members including Varo E. Tyler, Ph.D., Lilly Distinguished Professor of Pharmacognosy and retired dean of the Pharmacy School, Lyle E. Craker, Ph.D., a horticulturist from the University of Massachusetts, Norman Farnsworth, Ph.D., a senior research scientist at the University of Illinois Pharmacy School at Chicago and several of his colleagues. Also lecturing were Mark Blumenthal of the American Botanical Council, scientific author-photographer and lecturer Steven Foster, and Rob McCaleb of the Herb Research Foundation.

The course included lab sessions on distillation of volatile oils, high pressure liquid chromatography, NMR identification of contents of plant materials, and practicums in plant breeding and tissue culture. Also, there were field trips to Purdue's experimental farm where we observed several fields of basil and other herbs, the drying sheds, special planting equipment, and management methods, and to northern Indiana mint farms where we saw the field distillation units and talked to farmers about weed control. The class was taken to the Liebermuth Company in South Bend, importers of botanical products, and to the volatile oil company, Ray Brown & Sons in Bremen, Indiana. Then we spent a couple of days at the University of Illinois College of Pharmacy, where Dr. Farnsworth, Dr. Henry Fong, Dr. J. Fitzloff and staff lectured on several aspects of herbal medicine, scientific quality control projects and students got hands on experience with the NAPRALERT computer assisted search data base for natural products and a chance to observe some of the more recent laboratory advances in molecular chemistry.

Incidentally, horticulture is no longer solely a shovel and landscaping science, it is mostly molecular chemistry, genes and other similar scientific areas. A tidbit we learned was that lemon balm oil sells for $1,300.00 per pound. Want to know how much you have to grow and distill to get a pound?

In short, this course was a rejuvenating 10 days at Purdue, northern Indiana and Chicago, with appropriate social occasions to visit with the other students from around the world. Most of these students were post-doctoral researchers or government administrators in health and agriculture. This was only the second time Purdue conducted this course. I hope it becomes a popular course and other universities copy it so that you can have the same experience.

Jim Simon wondered out loud a couple of time about why a lawyer wanted to attend the aromatic and medicinal plants course. I believe his problem was that he kept forgetting that I was a pharmacist first and therefore his problem is the same as millions of Americans -- they do not know what pharmacists do or are capable of doing to help them with medicines.

The Purdue program also introduced me to the Lloyd Library in Cincinnati, which I had never visited before. So, on the way home and on a couple of other trips to Indiana this fall, I stopped in for several mornings and afternoons to get acquainted with the scientific and other literature in the field of phytomedicine, herbs and botanicals. Believe me, it is voluminous. And the literature sources are growing, with several new journals having started in the past year or so, and expensive. The Library was set up by heirs of John Uri Lloyd, a pharmacist and one of the founders of Lloyd Brothers, a company that made extracts and other botanical products primarily for eclectic physicians or "Indian" doctors, those who used herbal remedies the way American Indians had for centuries before the white man invaded. The Library is free, at least for now; it sells old reprints; contains a museum of Lloyds equipment and books; and is an interesting place for a scientifically curious person who likes interesting reading. Downtown Cincinnati has German and other ethnic restaurants to give you a pleasant break during the day.

Other Study Sources

Assuming Purdue does not conduct its New Crops course again until 1997, what else can you do to get a handle on the herb medicine business? Here are some suggestions.

- Contact the Texas Pharmacy Foundation to enroll in their home study courses for pharmacists on Herbs and Phytomedicines. They have three modules for a total of six hours of credit. They also conduct rainforest ethnobotanical ecotours for credit. Call the Texas Pharmacy Foundation at (512) 836-8350.

- At the University of Illinois an elective course in Contemporary Pharmacognosy is taught under Dr. D.D. Soejarto and C. Gyllenhaal. The phone number for the University of Illinois at Chicago College of Pharmacy is (312) 996-7240.

- One of the students I met at the Purdue course, Dr. Joseph Dalton, teaches an herb course at Ramapo College in New Jersey. No doubt there may be others, but not around the Maryland area.

The time I spent at the Lloyd Library gave me the opportunity to see what publications might be of help to practicing pharmacists. Here are a few of the journals and books, besides those already mentioned, that I would recommend that you take a look at as potential references as soon as you are ready to start on this new adventure.

Herbal medicine, phytomedicine, or just plain natural medicine is being used by billions of people across the world. Who can best advise on the use of these agents in the United States? How can we change U.S. law and get the FDA to accept the idea that herbal medicine may have some value? Knowing the science of something and not being frightened by it usually helps to make it legal. This is one reason I titled this article "Lawful Herbal Remedies." If it is scientific and it works, the remedies will be lawful and no one is going to sue you. If it is hocus pocus or you are simply too prejudiced to discover the scientific facts, then you may be sued. Lets all work to understand the science of plants and work toward achieving lawful herbal pharmacy in the US. It could save your life, or your life savings. **MP**

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[1] Pharmaceutical Research & Manufacturers of America, Drug Development and Regulatory Issues 2 (1994).

About the Author

William Skinner is a Maryland licensed pharmacist and attorney practicing in Montgomery County. He is a former past-president of the American Society for Pharmacy Law and has served on a number of committees for the Maryland Pharmacists Association. Dr. Skinner's area of expertise is in food and drug law.

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Jeanelle T. Beltran, Doctor of Pharmacy Candidate, UMAB School of Pharmacy

Imagine being quarantined in a convention hall with 5,200 pharmacists, students and scientists for five days. You live and breathe pharmacy daily, whether in the workplace or the lecture halls. You invite pharmacy into your homes in the form of pens and notepads. Why would you want more?

I admit that in the past I preferred to explore unfamiliar terrain than to twiddle my thumbs in the third row of Pharmacy Hall 101. Each return from a pharmaceutical convention brought me instant status as the "Robin Hood" of Pharmacy! Friends and family counted on me to shower them with my booty of highlighters and sample packs of Tylenol. Over the years, I realized that I am not attending these conventions as a registered looter and pillager of the exhibitors' booths. Behind those name badges are future employers, colleagues, and pioneers of this field that compose the lattice we call pharmacy. Would these folks hire a student who lurks in the shadows of continuing education sessions, pilfers plates of hors d'oeuvres, and slinks out the door before the speaker can utter "pharmaceutical care"?

As a three-year convention veteran, I finally discovered that I can gain more from these conventions than several canvas totes of goodies and five extra pounds of flab.

Which pharmacy track should I pursue? Individuals practicing various vocations within the pharmacy arena roam the convention halls. Inquire about the demands of their fields. Is this the type of practice you crave? How did they execute their goals and how long did it take? You have a future to nurture with the expertise of these potential mentors.

You want a job once you graduate or you have a strong desire to relocate. Before going to the convention, have several copies of your resume or curriculum vitae printed for distribution to prospective employers. Think of these initial contacts as round one of your interview. Therefore, I recommend that you refrain from sneakers, jeans, and a tee shirt during your quest for future employment and dress professionally. If economic restraints bind you, recycle one solid colored suit for everyday use with the aid of a collapsible iron and sewing kit.

You have **how many** *Continuing Education Credits to earn?* What a prompt and effective way to harvest CE credits from a field of topics! Conventions offer cutting edge information applicable to most practice settings. These educational sessions are opened to all attendees and are not restricted to only licensed pharmacy practitioners.

You have a voice so let it be heard. We do not live in a fascist society. Local and national pharmaceutical associations provide legislative bodies to develop policies, elect officers, and discuss key issues affecting the profession. How do you feel about certifying all pharmacy technicians? What is your stance on the sale of tobacco products in pharmacies? Will you support Ima Pharmacist as your next Member-at-Large? Stop your whining about the inadequacies of our profession and do something about it. Every one of you can shape our future and, above all, teamwork is important. Network with other students and practitioners, discover novel approaches, and implement these ideas into your institution of practice and learning.

As a student, did I gain anything from attending the American Pharmaceutical Association's Annual Convention in Nashville? With a Minolta camera as an appendage emanating from my neck, convention goers christened me as "that Media Girl." I also received employment offers, shook hands with the renowned photographer of National Geographic, Dewitt Jones, and increased my knowledge of Country music. So whether you are still in school or if you have practiced for 50 years, do not fall victim to the disease called apathy. Expand yourself and interrupt the monotony of life. Before you use this journal to line the bottom of your birdcage, tear out the page with the registration form (that's on page 22 if you haven't gotten that far yet) and sign up for the next convention, MPhA's! **MP**

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M687A AVHYAU

Charting A New Course

114th Annual MPhA Convention

June 16-19, 1996 ☆ Ocean City, MD

Charting A New Course!

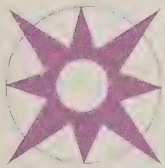
That's the theme for MPhA's 114th Annual Convention. It's a reflection of the exciting new direction that your professional association is taking to meet your needs today and tomorrow. MPhA has planned a challenging series of continuing education programs focusing on the issues facing pharmacists. In addition, we've provided for lots of time to relax and enjoy the beach at Maryland's premiere resort.

This year, MPhA convention attendees can earn more than 11 continuing education credits towards their relicensure requirements. Our business meetings have been scheduled to give everyone a chance to participate in the Association's policy decisions. If you've never attended a MPhA Convention, this is *definitely* the year to give us a try.

If you have any questions about the program, accommodations, or registration, please don't hesitate to contact the MPhA offices at (410) 727-0746 or toll-free in Maryland at (800) 833-7587.

Registration

To register for the Annual Convention of the Maryland Pharmacists Association, complete the registration form included with this packet. Please print or type clearly. Return the entire form, with your check or charge information for the total convention registration, to the address listed at the bottom of the form. You can also FAX your registration to MPhA at (410) 727-2253.



Admission to all functions will be by ticket or badge. Pick up badges and other registration materials at the MPhA Registration Desk beginning Sunday, June 16 at 1:00 pm or on Monday, June 17 beginning at 7:30 am. You must register with the MPhA Convention to take advantage of special convention hotel rates. Spouses or guests must register to participate in any convention special activities.

Full Adult Registration (Pharmacist, Spouse/Guest, Non-Member) includes tickets to all convention events. Child and Student Registration includes tickets to the President's Reception and entrance to the Exhibit Hall. Child or Student Registration *does not* include Crab Feast or Banquet tickets. These must be purchased separately. No admittance to the Trade Exposition will per permitted unless the individual is a registered attendee of the Convention.

Accommodations

Once again, the Maryland Pharmacists Association has been able to obtain for attendees discounted hotel rates for one of Ocean City's finest resort hotels.

In previous years, the hotel has sold out of reserved rooms at the special MPhA convention rate. Don't be disappointed! To reserve your room, call the Sheraton Ocean City Resort Hotel at (800) 638-2100. Be prepared to provide the Reservations Agent with your name, dates of arrival and departure, type of room requested and the number in your party. Tell the Reservations Agent that you are with the MPhA Annual Convention to obtain the special room rate!

All room reservations must be received by the hotel no later than June 1, 1996. Neither MPhA nor the Sheraton can guarantee space availability at these rates after the deadline.

Room Rates

Rates are subject to 8 percent room tax. One night deposit is required to guarantee your reservation. Children under 17 stay free-of-charge in same room as parents. Rooms are available for check-in at 3:00 pm. The Sheraton Ocean City Resort accepts personal checks for deposit only. A 72-hour cancellation or change notice is required.

Guest Rooms (per night)	
Single/Double	$130
Triple	$145
Quad	$160
Executive King	$150
Cabana Suites	$250
Studio Suites	$160

Condominiums (per week)	
With Maid Service	$1,200
Without Maid Service	$ 995

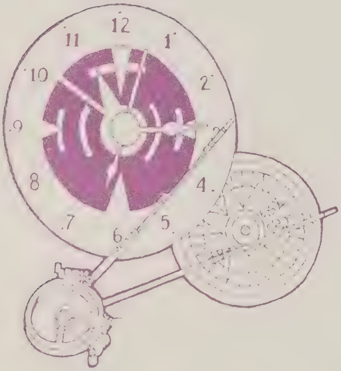
Sunday, June 16

1:00 to 5:00 pm
Registration
CRYSTAL BALLROOM TERRACE

2:00 to 4:00 pm
Welcoming Reception
CRYSTAL BALLROOM TERRACE

8:00 to 9:00 pm
Board Dinner with Students

9:00 to 11:00 pm
MPhA President's Reception
Enjoy an evening out in Ocean City and then join us in honoring the contributions and efforts of outgoing MPhA President Jim Tristani. Help us launch the start of our Convention with an "all you can eat" dessert buffet.



Social Events

This year's convention is full of excellent opportunities to network and socialize with your colleagues. From Sunday's Welcoming Reception to Tuesday evening's reception, banquet and desserts, you're certain to have a relaxing time!

And we guarantee you won't go home hungry! Join us every morning for breakfast, donuts and coffee during seminar breaks, luncheon in the Trade Exposition, and plenty of evening receptions and parties.

Monday, June 17

7:30 to 8:30 am
Bagel Breakfast
Sponsored by the Sheraton Hotel
CRYSTAL BALLROOM TERRACE

8:30 to 10:30 am
MPhA House of Delegates
First Business Session
The first session of MPhA's democratic governing body will be devoted to reports from MPhA's President, Treasurer, and Executive Director. In addition, nominees will be sought for the positions of House Speaker and Vice-Speaker. Speaker of the House Mark Sanford presiding.
CONFERENCE ROOMS 1,2,3

10:00 to 11:45 am
SAMPA Brunch and Flower Show
HORIZONS RESTAURANT

10:30 to 12:30 pm
Continuing Education Seminar
Just Getting Through The Day: Coping Skills for Pharmacists
With declining profits, rules and regulations that change practically every day, and more and more prescriptions, is it any wonder that pharmacists are suffering from frustration and burn-out? And now the profession is in the midst of changing its focus to patient care! This intensive seminar, featuring a nationally renowned speaker, looks at how pharmacists can cope with change, increase their own self-worth, and better handle the day-to-day challenges. The second part of this two-part seminar concludes this afternoon.

12:30 to 2:30 pm
Trade Exposition and Luncheon
CRYSTAL BALLROOM

2:30 to 4:30 pm
Continuing Education Seminar
Just Getting Through The Day -- Part 2
CONFERENCE ROOMS 1,2,3

6:30 to 9:00 pm
Annual Crab and Chicken Feast
BERLIN FIRE HALL

Tuesday, June 18

7:00 to
8:00 am
Continental Breakfast
CRYSTAL BALLROOM TERRACE

7:30 to
8:30 am
Board of Trustees Meeting
BREAKER'S PUB

8:00 to
10:00 am
Continuing Education Seminar
Pharmacy's Role in Integrated Health Systems
Continuing our theme of moving forward, this seminar focuses on what role pharmacists could play and what they have to do to position themselves to become a part of the future delivery systems.

10:00 to
11:30 am
SAMPA Brunch and Business Session
HORIZONS RESTAURANT

10:00 to
12:30 pm
MPhA House of Delegates
Second Business Session
House Speaker Mark Sanford and Vice-Speaker Crystal King will preside over the Second General Business Session. Part of the meeting will be dedicated to an open discussion of the organization's new direction and goals for the future of Maryland pharmacy.

12:30 to
2:30 pm
Trade Exposition and Luncheon
CRYSTAL BALLROOM

2:30 to
4:00 pm
Continuing Education Seminar
Managed Care and the Community Pharmacist
Following on last year's successful APhA/Schein Town Hall Meeting is this open discussion on how pharmacists can work through the maze of managed health care.

6:00 to
7:00 pm
MPhA Banquet Cocktail Reception
Sponsored by McKesson

7:00 to
9:00 pm
Annual Awards Banquet
Join us for the social event of the 114th Annual Convention as we honor outstanding members of the profession and congratulate our leadership.

9:00 to
10:00 pm
Coffee and Cordials Reception
Sponsored by AmeriSource

Wednesday, June 19

8:00 to
9:00 am
Bagel Breakfast
Sponsored by the Sheraton Hotel

9:00 to
11:30 am
Continuing Education Seminars
Before setting sail for home, join us for a series of refresher courses on concise reviews of important therapeutic classes and new treatments available.
CONFERENCE ROOMS 1,2,3

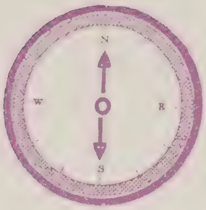
Trade Exposition

Keep up with the latest, most exciting developments and the newest products and services on the market at the MPhA Trade Exposition. Visit every exhibitor and enter to win the Grand Prize Sweepstakes!

Don't forget to join us for lunch in the Exhibit Hall on Monday, June 17 and Tuesday, June 18 from 1:00 to 2:30 pm.

Past exhibitors have included:

3M Pharmaceuticals
Alco Health Services Corp.
AMERICOM
Apothecon
Becton Dickinson
Bergen Brunswig
Boots Pharmaceuticals
Carex
Carlton Cards
Cerenex
Daniels Pharmaceuticals
Elegant Enterprises
Eli Lilly & Company
FoxMeyer
Fuji Trucolor Photofinishing
Geneva Pharmaceuticals
Glaxo
Goldline Laboratories
Hoechst-Roussel
Hudson Vitamins
Janssen Pharmaceutica
Konica Quality Photo East
Lederle Laboratories
MPP/EPIC
Marion Merrell Dow, Inc.
Mayer, Steinberg & Yospe
McKesson Drug
Medicine Shoppe Intl
Merck & Company
Miles
Novo Nordisk Insulins
Ohio Valley-Clarksburg
Owens-Brockway
Pfizer Labs
Pharmacists: prn
PharmaSTAT
Qualex
Robins/Ives Labs
Roche Laboratories
Schein Pharmaceutical, Inc.
Schering Plough/Key Pharmaceuticals
Searle Pharmaceuticals
SmithKline Beecham
The Upjohn Company
Travelers Express Company
UMAB School of Pharmacy
Valu-Rite
Warner Chilcott
Wyeth/Ayerst Labs
Zeneca Pharmaceuticals



Charting A New Course

Maryland Pharmacists Association ■ 114th Annual Convention
Sheraton Ocean City Resort Hotel ■ June 16-19, 1996

Registration

To register for the 114th Annual Convention of the Maryland Pharmacists Association, complete this registration form. Please print or type clearly. Return the entire form to MPhA at the address below or FAX it to us at (410) 727-2253.

You must register with the MPhA Convention to take advantage of special convention hotel rates. Spouses, guests and children must register or purchase function tickets to attend *any* convention events.

Full Registration includes admission to all meetings, social events, and processing of continuing education credits. Spouse/Guest Registration includes admission to all social events, plus the annual SAMPA Flower Show and Brunch. Single Day registration includes processing of continuing education credits for that day only. Tickets to social events for Single Day Registrants must be purchased separately. Children must also be formally registered to enter the Trade Exposition or other social events. The Child and Student Registration fees do not include the Crab Feast or Banquet.

Questions?
Call 800-833-7587
or 410-727-0746

MPhA
650 West Lombard St.
Baltimore, MD 21201

Do you wish to serve as an MPhA delegate at the business sessions?
☐ Yes ☐ No

Attendee Information

Name ____________________

Pharmacy/Company Name ____________________

Mailing Address ____________________

City/State/Zip ____________________

Telephone ____________________

Spouse/Guest Name(s) ____________________

Children Name(s) ____________________

Registration Fees

Please check the appropriate box(s).

	Before June 1	After June 1
Full Registration		
MPhA Member	☐ $ 150	☐ $ 175
Spouse/Guest	☐ $ 120	☐ $ 140
Non-Member	☐ $ 200	☐ $ 225
Child Under 18	☐ $ 10	☐ $ 20
Pharmacy Student	☐ $ 20	☐ $ 30
Daily Registration		
Single Day	☐ $ 40 ________ Day	☐ $ 50 ________ Day
Extra Event Tickets		
Crab & Chicken Feast		
Adult/Students	☐ $ 40	☐ $ 45
Child Under 12	☐ $ 15	☐ $ 15
MPhA Annual Banquet		
Adult/Students	☐ $ 25	☐ $ 30
Child Under 12	☐ $ 15	☐ $ 20
Sampa Events		
Flower Show/Brunch	☐ $ 15	☐ $ 20
Brunch/Business	☐ $ 15	☐ $ 20
Grand Total	☐	☐

☐ Enclosed is my check ☐ Bill my ____ VISA ____ MasterCard

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Litigation Update

Fraudulent Concealment

David B. Brushwood, R.Ph., J.D.

The Florida Court of Appeals recently reversed judgment for a pharmacy defendant in a case brought by a plaintiff who alleged harm caused by the pharmacy's negligent provision to a patient of numerous refills of the drug Voltaren without authorization from the patient's treating physician.

The trial court had granted summary judgment for the defendant pharmacy, dismissing the case brought by the husband of the patient, who had died of liver failure while using Voltaren. The lawsuit was brought also against the wife's treating physician, claiming that the physician issued multiple prescriptions of the drug without properly monitoring the side effects.

Although the two year statute of limitations had expired on the claim, the plaintiff contended that fraudulent concealment by the defendant pharmacy should permit the case to continue despite that expiration. Fraudulent concealment is an exception to the statute of limitations, based on the idea that the courts will not protect defendants who are directly responsible for delays in filing a lawsuit, because of their own willful acts. The running of the statute of limitations will be delayed when it can be shown that fraud has been perpetrated on the injured party sufficient to place that party in ignorance of the right to a cause of action or that the party has been prevented from discovering an injury.

According to the court, the plaintiff's attorney originally requested of the pharmacy a copy of the wife's prescription records, and the pharmacy provided a computer printout of the prescriptions which included a certification that "These drugs and medicines were dispensed to the above named person(s) by order of his (her) personal physician." The plaintiff asserted that the certification was fraudulent and that the pharmacy intended to conceal the fact that it dispensed drugs without a physician's authorization by producing this false document and by failing to produce its actual records as requested by the attorney. The pharmacy argued that these facts did not give rise to a claim of fraudulent concealment and that, even assuming fraudulent concealment, the attorney received the records of the wife's treating physician within the limitations period, and that these records should have shown the plaintiff that the physician did not authorize all of the refills.

The appellate court held that the fraudulent concealment argument was sufficiently credible to warrant further consideration by the trial court, and the case was remanded for further consideration. While the case has not yet been resolved, the principle has been recognized that untruthful statements about refill authorization may be the basis for defeating the dismissal of a claim for failure to file within the statute of limitations. One more good reason to assure that all refills are authorized! **MP**

Based on *Berisford v. Jack Eckerd Corporation*, 1995 Fla. App. LEXIS 12543 (November 29, 1995). Copyright 1996, David B. Brushwood. All Rights Reserved. Reprinted from *Dickinson's Pharmacy,* January, 1996.

At Issue

Should Pharmacists Prescribe?

Elaina Pepersack, Pharmacy Student
University of Maryland School of Pharmacy

In recent years, several states have legalized prescriptive authority for pharmacists. Many individuals however, question the wisdom and necessity of this decision. Recent developments in pharmacy include computer technology, robotics and technician certification. These advances illustrate the need for pharmacists to evolve beyond the traditional dispensing role and expand their practice in many new directions.

Currently, pharmacists may refer a patient to a physician, recommend an over-the-counter product, or suggest a non-medicinal solution to the problem.[1] To what degree, and in what manner does prescriptive authority represent a natural progression of the pharmaceutical profession?

The trend toward pharmaceutical care illustrates the evolution of the profession and supports the need to establish practical guidelines for pharmaceutical prescriptive authority.[2] Pharmaceutical care is ". . . the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patients quality of life."[3] The extensive training of pharmacists includes proper drug selection, dosing, interactions and costs. As a result, given a known disease state, a pharmacist possesses sufficient knowledge to effectively prescribe medication which improves a patient's quality of life and wellness.

Complete authority may successfully be granted to pharmacists for a limited number of medications used to treat diseases and conditions easily diagnosed. The state of Florida grants prescription privileges to pharmacists for a variety of conditions. The list includes oral, otic, or urinary analgesics, hemorrhoid medications, leg cramp medications, antihistamine and decongestant combinations, anthelmintics, topical antifungals, keratolytics, vitamins with fluoride, and medicated shampoo with lindane.[2] This policy enables a patient to receive effective treatment without the cost of going to a doctor.

The profession benefits by evolving beyond simple dispensing to a higher level of involvement in patient care.

Additionally, limiting the number of sites the patient must visit before receiving medication reduces waiting time and inconvenience. The profession benefits by evolving beyond simple dispensing to a higher level of involvement in patient care. This direct involvement justifies funding private consultation areas in pharmacies.[4] Lastly, physicians benefit by reducing the number of unnecessary office visits and pharmacist's phone calls verifying prescriptions. This additional time permits physicians greater access to patients requiring their specific diagnostic abilities.

In addition to the profession of pharmacy, the economic evolution of the entire health care system may be accomplished by granting pharmacists limited prescriptive authority. Opposing physicians fear that competition from pharmacists would have a negative economic impact on their practices, and the apparent overlap of duties may cause conflicts. Research in this area has shown that this is not the case. Pharmacist's prescriptions represented less than one percent of those written in Florida throughout the duration of the study.

Furthermore, as a result of current law, surveys show that both prescribing and non-prescribing pharmacists perceived no change in their relationships with physicians.[5] This preliminary data suggests that health care may conceivably evolve to allow the pharmacy to be used as a filter eliminating unnecessary trips to a doctor and eventually reducing the overall costs of medical services.

Maintaining current pharmaceutical responsibilities, as well as, incorporating prescriptive authority into established practices comprises the ideal outcome of the Florida law. Critics complain that patients may delay in consulting, or not consult their physicians at all if the pharmacist could prescribe medication. They argue that this exclusion or delay would lead to significant complications and adverse health effects for the public. The incorporation of the Florida law did not involve sacrificing any referrals pharmacists made to physicians. These conclusions are evidenced by the survey conducted by the University of Florida's Department of Pharmacy Health Care Administration supported by a National Association of Chain Drug Stores (NACDS) grant which studied the effects of the Florida law.[1]

Both pharmacists and physicians agree that pharmacists lack the diagnostic skills necessary to prescribe *all* medications; however, disagreements exist in establishing the criteria and scope of pharmacy-based care. Many physicians oppose prescriptive authority for pharmacists beyond over-the-counter medications. They feel that pharmacists lack the ability to distinguish minor problems from those requiring a physician's care. Again, Florida's evidence shows that this is not the case. There have been no malpractice lawsuits against prescribing pharmacists, nor have there been any instances of privilege abuse.[6] Additionally, inexpensive liability insurance is available to pharmacists who choose to prescribe medication.

While Florida permits pharmacists to prescribe without a physicians approval, several states require a doctor to review a pharmacists prescriptions. South Dakota's Revised Pharmacy Practice Act represents a conservative alternative to complete prescriptive authority. Pharmacists may initiate or modify drug therapy by protocol or other legal authority established and approved by a practitioner authorized to prescribe drugs.[7] Other states with similar laws include Mississippi, New Mexico, Oregon, and Washington. Prescribing under the authority of a physician according to protocol opens the door to prescribing independently; however, it does not effectively utilize the potential of pharmacists as knowledgeable drug experts. Additionally, verification issues potentially create unnecessary paperwork and phone calls which consume time better spent counselling patients.

California's law, on the other hand, extends the responsibilities of pharmacists located in licensed health care facilities to initiating and modifying drug therapy, preforming physical assessment, ordering necessary laboratory tests, and administering drugs by injection under protocol. This law encompasses institutional issues and allows the possibility of future pharmaceutical practitioners. Nevertheless, California pharmacists are still limited to practicing under physicians in limited clinical settings. Expanded diagnostic and clinical activities such as ordering lab tests and administering injectable drugs may occur at the expense of services for which the pharmacist is uniquely qualified. Furthermore, using pharmacists primarily as assistants to physicians assistants is an inefficient use of health resrouces and professionals.[5]

Complete prescriptive authority for pharmacists restricted to a limited scope of medication for disease states easily recognized represents a viable national policy. Evidence gathered in Florida indicates that prescriptive authority has not lead to interprofessional conflicts, decreased physician referrals, malpractice lawsuits or abuse of power. Florida's law makes benefits available for the patient, pharmacist and physician alike. Other states have demonstrated that pharmacists may prescribe under physicians; however, this may lead to misuse or underutilization of professional skills as well as creating extra work. The benefits gained by permitting pharmacists to prescribe medication far outweigh any of the physicians' concerns. The ability of pharmacists to effectively assist physicians in the neighborhood drug store provides the health care community with a viable alternative to the spiraling health costs and lack of resources.

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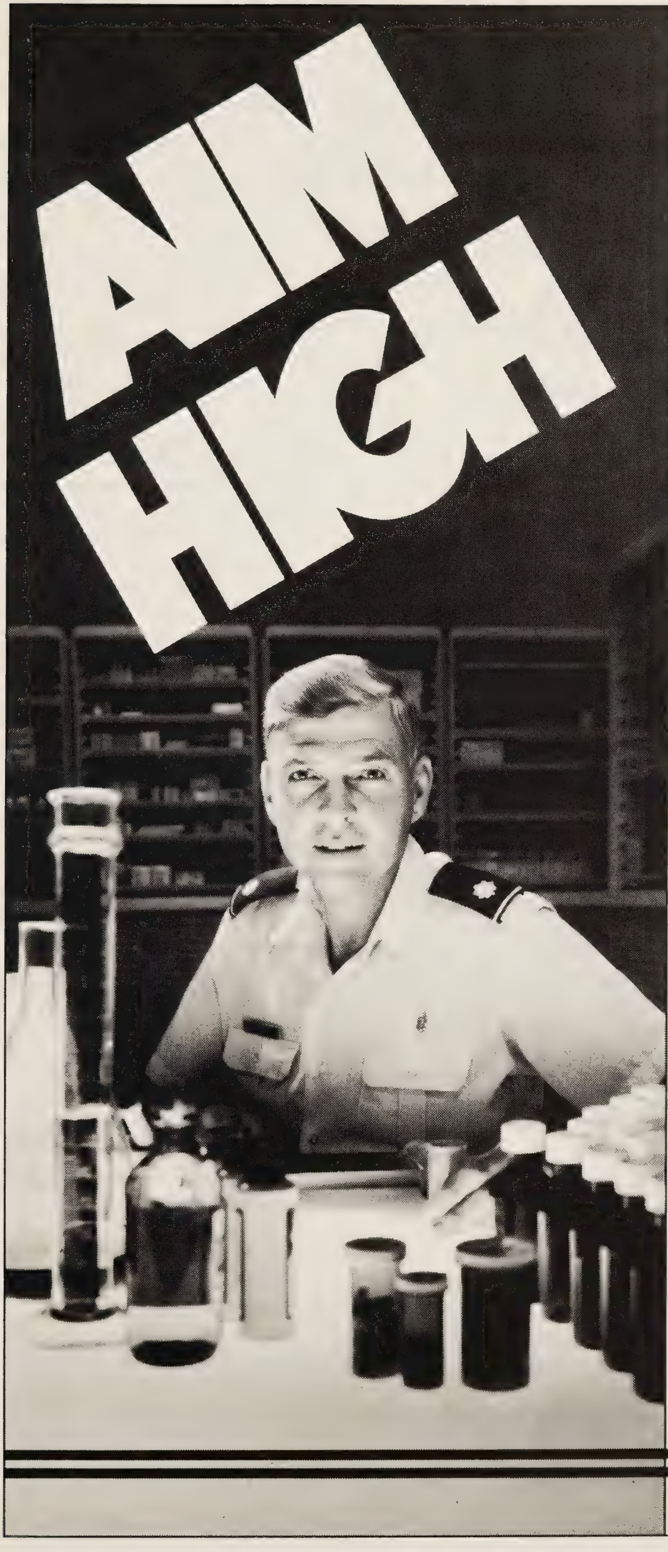
MP



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AIR FORCE

Pharmacists Rehabilitation Committee

Annual Report for 1995

The Maryland Pharmacists Rehabilitation Committee is a group of dedicated pharmacists who have volunteered their time and efforts to helping chemically or otherwise impaired colleagues. Originally part of the Maryland Pharmacists Association, the PRC works closely with MPhA, MSHP, the School of Pharmacy, and the Maryland State Board of Pharmacy. Its record of success is due directly to its volunteers and to the continued support of professional organizations. This Annual Report to the profession is designed to show what we have accomplished for pharmacy in 1995.

Financial

The total budget of the committee in FY95 was $10,805. Funding was provided in part by the Maryland State Board of Pharmacy (46%), the Maryland Pharmacists Association (13%), the Maryland Society of Health-systems Pharmacists (5%) and other sources, primarily individual contributions (36%).

Outlays for committee operations are: Salary (76%), Printing and copy costs (11%), Communications (1%), Diagnostics (7%), and Fees and Overhead (5%).

Case Summary

During 1995 we initiated nine new contracts and closed out three cases. Additionally we were involved with three pharmacists and four pharmacy students who, while not chemically dependent, were seeking information regarding referral or treatment options for either themselves or family members. At the close of the year we are handling 27 active cases.

We are experiencing a trend toward longer contracts as Board referred pharmacists (about 50% of cases) are being required by the Board to continue under PRC supervision for several years after discharge from their treatment program.

Highlights

Stability and administration of the committee.

The committee faced significant challenges during 1995. Among these were the departure of Chairman, Harry Finke, and the attrition of two additional long standing committee members. These losses increased the time demands on the remaining volunteer members. The year was one of decreasing financial contributions during a period of increasing reporting demands related to Board referred cases. Throughout this time of hardship, the committee maintained its schedule of monthly meetings wherein members cover routine business and review the cases being followed.

Between meetings the committee collects the tracking data needed to describe the recovery progress of its cases. These include reports from the recovering pharmacist's therapist, the employer (whether in or outside pharmacy practice), and the PRC monitor who communicates with the recovering pharmacist on a weekly basis. The objective of this reporting and data collection system is to ensure that the recovering pharmacist is complying with the PRC treatment contract. These data are collected and maintained by the PRC coordinator who is the only paid staff.

New Chairman

In 1995 the PRC elected Milton Moskowitz as the new chairman.

New Law

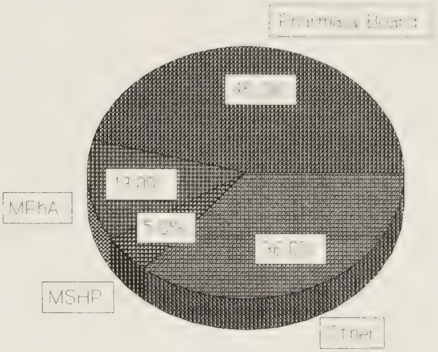
In the September 1995 issue of the *Maryland Pharmacist* PRC president Tony Tommasello describes the history of Senate Bill 329, passed on May 18, 1995, which enables the Board of Pharmacy to provide funding to the PRC. This ensures that the PRC will be able to follow Board referred cases and fulfill the reporting requirements listed in the pharmacist's Consent Order for eventual reinstatement of full practice privileges.

New member

Pharmacist Rick Peterson joined the PRC bringing with him the expertise of past employment as an addictions counselor and researcher.

Sources of PRC Funding

July 1, 1994 to June 30, 1995



Activities to improve the environment of treatment for pharmacists in the State of Maryland.
The committee established a new 12-step program for pharmacists in Gaithersberg, Md. It has been difficult for pharmacists to locate an AA or NA "home group" of recovering health professionals where he or she can expect to encounter the same faces on a regular basis. This group is the first of its kind for pharmacists in Maryland and is open to our colleagues in recovery, irrespective of their association with the PRC program.

New treatment linkages have been forged with addictions providers in Frederick and Hagerstown to strengthen services in western Maryland. In addition, new treatment providers on the Eastern Shore have been added to our list of referral sources.

The committee was instrumental in identifying and supporting five student attendees to the Utah Summer School on Alcoholism and Other Chemical Dependencies. These students join the existing ten who preceded them in past years.

The Fred Moskowitz Fund was established five years ago to ensure that financial barriers to treatment are eased through a low interest, deferred payment loan program. It is a dedicated account, funded through contributions, in order to make loans to recovering pharmacists. The fund is modest but successful in that six pharmacists have benefited by the availability of resources to assist them and their families facing economic hardship during the period of treatment. Recipient pharmacists do not receive unrestricted cash allocations. Instead, this program has held families together when income was significantly curtailed, by making a mortgage payment or paying for other necessary living expenses.

Spin-off Projects
The PRC has been an active force in raising the level of awareness to drug abuse related issues among the pharmacy school student body. Each year the committee invests in the training of one or two students, selected on the basis of their stated interest in helping fellow students and in advancing the principles of the PRC while in school and after graduation. The PRC works hand in hand with other campus programs in the process of selecting and sponsoring student attendance at the University of Utah Summer School on Alcoholism and Other Chemical Dependencies. There is currently a cadre of nine active pharmacy students who completed the Utah program.

This group has assumed a leadership role in the campus drug and alcohol abuse prevention campaign. Pharmacy student Tom Carguilo (class of 1997), a graduate of the 1994 Utah program, is the chairman of the campus wide group "Students for Drug Awareness and Prevention" which boasts representation from each of the six professions at UMAB. He is joined by pharmacy classmates Kim Mecler, Aatif Sheik, Jaye Wexler, and second year students Sandra Werking, Chris Kahley, Suzanne Morseburger, Misu Choi, and Anne Graffunder in their efforts both in the Pharmacy School and campus wide.

As SDAP chair, Mr. Carguilo is an ex-officio member of the Interprofessional Drug and Alcohol Program (IDAP) committee. IDAP is an interprofessional group of UMAB faculty, with participation by Dentistry, Law, Medicine, Nursing, Pharmacy, and Social Work, dedicated to ensuring that substance abuse and dependence concepts are addressed in each discipline's core curriculum and to enhancing the elective offerings on substance abuse in each school on campus. IDAP and SDAP are companion programs with faculty from each school working synergistically with their students to make curricular and programmatic advances across campus.

SDAP members perform breath alcohol monitoring at campus social functions, promote the "0,1,3" moderate drinking guidelines[1], produce and disseminate substance abuse awareness materials, and provide alcohol free (mocktail) beverage service at campus social functions. The SDAP group is sponsored by the UMAB Office of Academic Affairs which signifies the level of commitment that has developed on campus toward this issue.

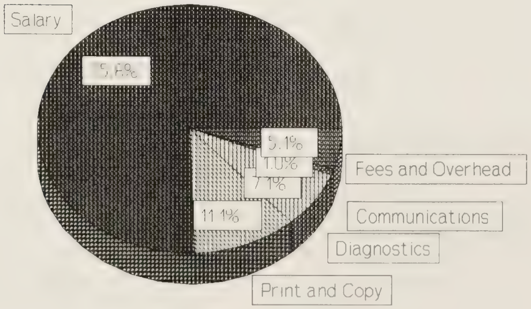
Efforts Underway

C.E. programming has been conducted in the past to help pharmacy owners and supervisors recognize a substance abusing impaired pharmacist and make a referral to the PRC. The May 1992 issue of *Maryland Pharmacist* was dedicated to this topic and provided C.E. credits to those who completed the post-test. The School of Pharmacy has incorporated these learning objectives into its core curriculum and the medical literature is more than adequate on this topic. The PRC stands ready to provide assistance to individuals in supervisory positions as the need arises.

Now is the time to shift the emphasis from recognizing impairment to measuring recovery. Treatment, rather than dismissal of an employee pharmacist, is a rational business decision since hiring and retraining costs often exceed the expense of effective drug abuse treatment. Employers who hire or retain recovering pharmacists must make judgements of job readiness and capability. As with other diseases that require temporary departures from the work setting, the returning pharmacist may need to ease back into the job. Supervisors need the information and skills to distinguish between behaviors indicative of recovery from those that suggest relapse.

PRC Expenditures (% of Total)

July 1, 1994 to June 30, 1995



The PRC cannot operate from a shrouded posture. Despite the sensitive and confidential nature of its business, the PRC needs open avenues of communication and discussion with the pharmacy community. Some of this can be accomplished through C.E. programs and a steady stream of discussion about the content of annual reports, both of which have been lacking in recent years. This requires a partnership with pharmacy leaders at the state and local levels. Committee members are prepared to respond to invitations to meetings and other forums that provide this opportunity.

On-going Challenges

Reporting self-referred non-compliant pharmacists to the Board of Pharmacy continues to be a taxing and potentially volatile issue. The PRC has worked hard to develop trust with impaired pharmacists, moving toward the desirable goal of encouraging pharmacists in need of support and advocacy to seek services. The mission is not to shield an individual from accepting the responsibility of their actions (in fact just the opposite is true) but to create an environment that encourages self identification and confidential treatment intervention as an alternative to Pharmacy Board prosecution and public sanction. The gains made in this effort can easily and rapidly be lost if the PRC adopts a practice of abandoning the pharmacist at the slightest hint of imperfect compliance with a demanding treatment contract.

On the other hand the committee is extremely sensitive to the public health risks and the potential damage to the image of pharmacy that accompany failed treatment or relapse. It is clear that unless the committee maintains a program of integrity on this point, it risks losing the support of both the Board and the pharmacy community. Therefore our policy, exercised on a case by case basis, has been to work with a self-referred pharmacist in complete confidence unless the committee determines that referral to the State Board is necessitated by the pharmacist's actions jeopardizing either of those areas of concern.

A new strategy was adopted this year in cooperation with the Board of Pharmacy. A non-compliant pharmacist can choose voluntary license surrender in lieu of having the non-compliance reported to the Board of Pharmacy with a recommendation for emergency license suspension. This places the decision squarely on the shoulders of the pharmacist who must discontinue pharmacy practice. Either action removes the pharmacist from the work place until the impairment is addressed in a program of therapy.

Funding stability has improved dramatically with the passage of SB 329. However fairness and equity issues need to be addressed. Appropriate cost sharing, rather than reliance upon state funds, is the goal of the Committee's budgetary process. This process must be responsive to those who give generously to the program, and to the accounting requirements of the state fiscal system. This year the PRC has both received state funds and established accounting procedures that satisfy the auditing guidelines of the state.

The current PRC committee members are: Gil Cohen (Treasurer), Jeff Farace, Milton Moskowitz (Chairman), Rick Peters, Toni Pluchinski, Gerry Roberts, Barry Thomas, and Tony Tommasello (President). Members who either resigned or requested a leave during the past year are Harry Finke, Tim Muth, and Randy Delcher. They are available to any Maryland pharmacist who needs advice or assistance. To contact the PRC, call (410) 706-7513 for a confidential consultation **MP**

---

[1] 0 drinks if pregnant, recovering, or scheduled to perform clinical duties within 24 hours; no more than 1 drink per hour; no more than 3 drinks per event.

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Patient Counseling
Lyme Disease

Thomas A. Gossel, R.Ph., Ph.D., Dean
Ohio Northern University

J. Richard Wuest, R.Ph., Pharm.D.
Professor of Pharmacy Practice, University of Cincinnati

A professional development program made possible by
an educational grant from **SEARLE.**

Lyme disease (Lyme borreliosis) is an infection that involves a large number and variety of the body's organ systems including the skin, nervous system, heart, and joints. There is also a significant immunologic component. Its outcome is often difficult to predict.

Although first noted in Australia in 1887 and described in Sweden in 1909, it wasn't believed to be a serious problem in the U.S. until 1975. At that time, an unusual geographic clustering of what appeared to be juvenile arthritis was reported in three communities: Lyme, Old Lyme and East Haddam, Connecticut. It is thought that the disease spread to the U.S. from Europe via infected rodents or domestic animals which were brought on board ships, or by infected ticks hitching long distance rides on migrating birds.

With more than 10,000 new cases of Lyme disease reported each year, it is now the most commonly occurring tick-borne illness in the U.S. While it can cause considerable debilitation and even death in some individuals, others suffer no serious problems from the disease.

With outbreaks now reported on all other continents except Antarctica, the three endemic areas where Lyme spirochetes, ticks, mice, and deer are common include the Northeast coast, the upper midwest (specifically Minnesota and Wisconsin), and the West Coast (especially California, Oregon and western Nevada). These areas are enlarging each year, because the ticks have been found on more than 30 species of animals and 50 types of birds.

The Disease

A spirochete, *Borrelia burgdorferi* is the organism that causes Lyme disease. It is transmitted through bites of deer ticks (*Ixodes dammini and I. pacificus*) primarily, as well as those of other species. The white-tailed deer and white-footed mouse are the most common mammals that serve as intermediate hosts to humans.

Ticks feed only once during each of the stages of their two-year life cycle -- larva, nymph and adult. Larva usually pick up the spirochete in late summer from ingesting the infected blood of a white-footed field mouse (in the Northeast) or a wood rat (in the West). These bacteria are harmless to the rodent. The following spring, larva molt into nymphs, still housing the spirochetes in their gut. Nymphs that bite a human transmit the bacteria through their saliva as they feed. Nymphs also bite mice, perpetuating the chain of infection by depositing bacteria in the rodents' blood where a future bite by another tick can spread the infection. In the fall, the ticks, now mature adults, prefer to feed on deer. Deer, like mice are not affected adversely by the bacteria. They provide a mating site and are vectors to transmit *B. burgdorferi* to another generation of ticks.

Tick bites and resultant Lyme disease may occur at any time of year, most commonly May through November. The largest number of cases is reported during late spring and early summer (June and July). This suggests that ticks in nymphal stages transmit the disease most readily. Adult ticks occasionally transmit the disease when they feed in the autumn.

There is a direct correlation between the risk of infection and the duration of tick attachment. In experimental studies, most ticks remain attached for 24 hours or more before transmission occurs. Thirty-six to 48 hours may even be a more realistic time before an infectious dose of *B. burgdorferi* is transmitted. Infection rate in *I. dammini* ticks is high. In endemic regions of Connecticut and Shelter Island, New York, the Lyme disease spirochete has been found in 35 percent and 61 percent, respectively, of these ticks.

Following infection with the spirochete, there is an incubation period of 3 to 32 days. The organisms then migrate outward in the skin. This results in eventual spread by the lymph system (regional adenopathy) or dissemination in blood to organs throughout the body where the spirochete may persist for years.

Clinical Characteristics

The classical course of Lyme disease is conveniently characterized by three stages with different manifestations associated with each stage. The three stages of progression of Lyme disease are State 1 (dermatologic), Stage 2 (neurologic and cardiac), and Stage 3 (rheumatologic).

Stage 1 -- Dermatologic: The dermatologic hallmark for Lyme disease, that is present in up to 85 percent of all cases and is the most important clue to early diagnosis is erythema chronicum migrans (ECM). This starts as a small, red (erythematous) rash about the size of a quarter. There can be central punctum or a mark from the original bite. It appears within several days to several weeks following a bite from an infected tick, and may fade in a day or two. Common bite sites include the thigh, groin, forearm and armpit (axillae) areas. Biopsy of a lesion may reveal the presence of spirochetes.

ECM may expand in size to a much larger area. Areas measuring up to 70 cm in size are not uncommon. This characteristic lesion that resembles a severe rash is denoted by a bright red, raised border, and has a partial central clearing ("bulls-eye" appearance) exhibiting a bluish color before it resolves. Skin lesions may feel warm to the touch, and patients may describe the condition as a burning and itching sensation that is not generally painful.

Several days after infection, the spirochete may enter the blood and lymph to initiate development of secondary lesions. Other skin manifestations include conjunctivitis, photosensitivity reactions, and urticaria.

Treatment Guidelines for Lyme Disease*

Erythema Migrans

Adult dosage[1]: doxycycline 100 mg PO BID or amoxicillin 250 to 500 mg PO TID.

Pediatric dosage[2]: >9 years: doxycycline 100 mg PO BID; <9 years: amoxicillin 25 to 50 mg/kg/day PO divided TID.

Bell's Palsy

Use regimen for erythema migrans.

Serious Nervous System Disease[3]

Adult Dosage: Ceftriaxone 2 g/day IV or Penicillin G 20 to 24 million units/day IV in divided doses every 4 hours.

Pediatric dosage: Ceftriaxone 75 to 100 mg/kg/day IV or Penicillin G 300,000 units/kg/day IV in divided doses ever 4 hours.

Arthritis (new onset)[4]

Use regimen for erythema migrans. If amoxicillin is used, use higher doses: 500 mg TID for adults, 50 mg/kg/day divided TID for children.

Arthritis (recurrent or persistent)

Use regimen for serious nervous system disease.

Carditis

Primary AV block with PR interval <0.3 seconds and no symptoms, use regimen for erythema migrans. Primary AV block with PR interval >0.3 seconds or second degree or complete AV block, use regimen for serious nervous system disease.

References* *Med Lett 34:95-97, 1992; Pediatrics 88:176-9, 1991.*

1. *Oral regimens generally given for 10-30 days; IV regimens for 14-21 days.*
2. *Do not exceed adult dosage.*
3. *Includes meningitis, encephalitis, neuropathy, encephalopathy.*
4. *In patients untreated for Lyme disease.*

Table One

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Dermatologic abnormalities normally resolve over several weeks. Any or all of them may recur.

The dermatologic conditions may be reported with other clinical manifestations concurrently, almost always with generalized malaise. These may occur before the onset of ECM, with malaise often continuing after resolution of skin lesions. A flu-like syndrome consisting of chills, fatigue, fever, headache, malaise, and regional lymphadenopathy (enlargement of lymph nodes may be present. All or some of these manifestations may persist for several weeks.

Patients with extensive skin lesions may display a classic clinical presentation that includes abdominal pain, sore throat, cough, severe headache, signs of meningeal irritation, mild encephalopathy, widespread musculoskeletal pain, generalized lymphadenopathy and/or splenomegaly (enlargement of the spleen), hepatitis, and in males, testicular swelling. These conditions are generally intermittent and changing in nature except for malaise and fatigue which can be very persistent and disabling.

Stage 2 -- Neurologic and Cardiac: Stage 2 may not appear for weeks to months after the onset of Stage 1. Headache is the most common neurological finding. This is consistent with irritation of the meninges, and may be accompanied by pain, stiffness or pressure in the neck. Fever, facial (Bell's) palsy, abnormal muscle movements, and impairment of cognitive function may occur. Reports indicate that nearly 40 percent of patients experience meningitis and cranial neuropathy in various combinations.

Approximately 60 percent of untreated patients develop some degree of arthritis during this stage. It is generally transient and asymmetric, and involves many joints, most commonly the knee.

Neurologic pathology may continue for months, become latent, then recur. Proper treatment will resolve the neurologic abnormalities. Patients unresponsive to therapy may continue to display persistent or progressive symptoms of the disease.

Cardiac conduction disorders and myocarditis may appear within several weeks following onset of disease. They are rare, occurring in fewer than 10 percent of patients.

Atrioventricular block (AV block) is the most common cardiac complication. A temporary pacemaker may be inserted in patients with complete heart block. Cardiac involvement of lesser frequency includes cardiomegaly, mild left ventricular dysfunction, and myopericarditis (combined pericarditis and myocarditis). The heart's valves are usually not affected.

Depending on the severity of the condition, patients with Lyme disease may or may not display cardiac symptoms. When present, cardiac involvement is usually temporary and last between three days to six weeks. However, it can recur.

Stage 3 -- Rheumatologic: Within a poorly defined period spanning several weeks to two years following onset of symptoms, rheumatologic manifestations resembling arthritis develop in more than 50 percents of patients. Widespread pain in the joints, tendons, bursae, muscle or bone are the early abnormalities observed. These symptoms appear during any stage of Lyme disease, but are most intense in Stage 3. Musculoskeletal pain early in the disease usually affects a small number of body areas and generally lasts from several hours to several days.

More intense rheumatologic findings can appear later. These include intermittent arthritic attacks with significant pain and swelling of affected joints. These attacks typically involve the large joints -- mainly the knee, shoulder, and hip. The temporomandibular joint, fingers, hands and wrist are also often involved.

Patients may complain of fatigue concomitant with joint pain, but other systemic symptoms are uncommon in Stage 3. The duration of these intermittent episodes may persist for hours, days or weeks. They may recur for several years. Approximately 10 percent of patients will suffer from chronic joint involvement with persistent inflammatory arthritis. Cartilage and bone destruction similar to that of rheumatoid arthritis may occur.

Diagnosis of Lyme Disease

Since early states of Lyme disease can mimic various viral infections, diagnosis of infected patients is often complicated. The rapidly changing course of the disease is an important clue to its spirochetal etiology. Approximately 40 to 50 percent of patients with early stages of Lyme disease may not exhibit a positive Lyme serology or other laboratory evidence of the infection. Thus, in the early stages of symptom onset, a presumptive diagnosis is frequently based on the presence of dermatologic manifestations and/or history of travel to an area of the country linked with the infection. Nearly one-half of all patients with Stage 2 and 3 Lyme disease do not remember a preceding skin rash or tick bite.

A differential diagnosis should be considered for any patient who is suspected of having Lyme disease. Rheumatoid arthritis and systemic lupus erythematosus can also cause many of the same symptoms of Lyme disease.

Patients who have late developing complications of Lyme disease may be diagnosed on the basis of both clinical symptoms and serological test results. For example, persons demonstrating atrioventricular block without an apparent cause should be tested further as part of a cardiac work-up for possible Lyme disease.

Treatment of Lyme Disease

Therapy must be started as soon after the onset of illness as possible. Prompt antimicrobial therapy can decrease the duration of the rash and prevent development of further manifestations of the disease. However, early and appropriate treatment does not guarantee against the appearance of subsequent complications.

Prevention Tips for Avoiding Lyme Disease

- Wear protective clothing in the woods and grasslands, and especially where these two areas meet. Wear long pants and long-sleeved shirts that are tight around the ankles and wrists; tuck pants into socks; wear shoes that cover the entire foot; and wear light-colored clothing so that ticks can be seen easily.
- Use repellent containing permethrin or DEET, but don't overdo it; children can have difficulty if they breathe in too much repellent spray.
- If you visit the woods, check for ticks upon returning. Closely check hairy parts of the body, and examine pets as well. Ticks prefer rodents and deer, but will hop onto almost anything warm and furry. Wild animals can harbor the spirochete without becoming ill; domestic animals can develop symptoms of Lyme disease.
- If you find a tick, remove it with tweezers. Place the tweezers on the head of the tick as close as possible to the skin. Pull upward, slowly and steadily at a 45 degree angle, being careful not to squeeze the tick. Wash your hands. Apply an antiseptic, such as rubbing alcohol to the bite area.
- If possible, save the tick in a closed jar, labeled with the date of biting, until you are certain that Lyme disease has not developed. Then, bury, burn or flush the tick. Do not use nail polish, gasoline, a hot match, oils, or petroleum jelly to smother or kill the tick. Any of these measurers may prompt the tick to inject the spirochete into your blood.
- Shampoo pets regularly throughout the spring and summer with a soap that will kill ticks. Brush them daily, outdoors. Do no allow pets to lie on furniture or sleep with humans.

Source: *FDA Consumer*, June 1994, page 8.

Table Two

Antimicrobial therapy is usually based, initially, on the in vitro susceptibility patterns of the pathogen. The susceptibility of *B. burgdorferi* can differ significantly in vitro and in vivo.

Treatment guidelines for children and adults with Lyme disease are summarized in Table 1. Oral antibiotic treatment for a minimum period of 10 days is recommended for patients with Stage 1 disease. Treatment of cardiac and neurologic complications requires more aggressive therapy over a longer period to increase the chance for remission. In Lyme disease-induced arthritis, several months of therapy may be required for complete resolution of symptoms. The intravenous route is required to achieve adequate blood levels to treat severe conditions effectively.

There are reports that correlate *B. burgdorferi* with teratogenesis. When women have contracted the disease in their first trimester of pregnancy, congenital cardiac abnormalities, encephalitis, spontaneous abortion, and sudden infant death have resulted. In a retrospective review of 19 cases of Lyme disease during pregnancy, five were associated with adverse fetal outcomes. Therefore, it is recommended that females exposed to *B. burgdorferi* or those who acquire Lyme disease during pregnancy be treated promptly.

Patients with Lyme disease may display symptoms of the Jarisch-Herxheimer reaction, a transient condition that follows initiation of massive doses of antimicrobial therapy. The reaction results from rapid antigen release form the spirochetes leading to a generalized inflammatory reaction. It is characterized by fever, headache and joint aches which may have been misinterpreted as an exacerbation of the illness.

Other drugs are prescribed when needed. These include topical antipruritics, analgesics, and anti-inflammatory agents.

Counseling Patients on Lyme Disease

In the U.S., more vector-borne disease is transmitted by ticks than by any other pest. During the past two decades, increasing numbers of people have migrated to rural areas and increased their recreational activities. Therefore, the likelihood of tick encounters is greatly enhanced.

Individuals in high risk areas should be familiar with the type of tick that transmits Lyme disease in their area. They should understand how the spirochete is transmitted and how it behaves in the human body. Most importantly, they should know the signs and symptoms of Lyme disease, and that, without exception, physician intervention is essential.

Quick removal of a tick can prevent disease transmission. Anyone potentially exposed should examine himself carefully after each outdoor exposure. He should pay special attention to the head, neck, ears, axillae, naval, buttocks, and groin.

A number of repellents that contain DEET (n, N-diethyl-m-tol-butamide) or permethrin can be used during forages through grassy fields and wooded areas. Ticks can also be found on well maintained suburban lawns. These products can be applied directly to skin or clothing and are effective when used correctly. Information in Table 2 will be helpful to prevent tick-borne infections and can be passed along to consumers.

Patients with Lyme disease need to understand the importance of complying with physicians' instructions. Antibiotics can be curative, but they must be taken as directed. **MP**

CE Info

Goals

The goals of this lesson are to discuss the etiology, prevention and treatment of Lyme disease, to describe how to remove ticks from the skin, and to suggest advice that can be conveyed when counseling.

Objectives

At the conclusion of this lesson, successful participants should be able to:

1. select from a list, the cause and/or physiologic factors associated with Lyme disease;
2. differentiate between the signs and symptoms, and other characteristics of Stages 1, 2 and 3 of Lyme disease;
3. identify specific drug therapy for Lyme disease and specify pharmacologic and toxicologic characteristics of the drugs;
4. choose from a list, the correct steps to remove a tick from the skin; and,
5. demonstrate and understanding of how to counsel patients on the causes, prevention and treatment of Lyme disease.

CE Quiz

MPhA members can receive one contact hour of ACPE approved continuing education by completing and returning the CE Quiz that appears on page 38 of this issue.

This program has been approved for one credit hour (0.1 CEU's) of ACPE approved continuing education. The Maryland Continuing Education Coordinating Council is an approved provider for continuing education programs for pharmacists by the American Council on Pharmaceutical Education. **ACPE #144-999-96-014-H01.**

Continuing Education Quiz

May/June 1996 -- Lyme Disease

This month's questions are taken from the article on Lyme Disease that appears in this issue. Circle your answers to the following questions and mail the entire page to *Maryland Pharmacist CE*, 650 West Lombard St, Baltimore, MD 21201-1572 or FAX it to (410) 727-2253. There is **no charge** for this quiz for MPhA members (non-members $5.00). The completed quiz for this issue must be received by June 30, 1997. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly. **ACPE #144-999-96-014-H01**

Name ______________________________

Address ______________________________

City/State/ZIPCode ______________________________

1. Lyme disease was originally discovered to be a problem in the United States because of an unusual clustering, in Lyme CT, of what appeared to be:
    a. chicken pox.
    b. juvenile arthritis.
    c. Reye's syndrome.
    d. scarlet fever.

2. Lyme disease is transmitted by:
    a. fleas.
    b. lice.
    c. mosquitoes.
    d. ticks.

3. While Lyme disease can occur anywhere, the area of the country where it is *least likely* to be endemic is the:
    a. Northeast.
    b. South.
    c. Upper Midwest.
    d. West.

4. The three stages of progression of Lyme disease include all of the following *EXCEPT:*
    a. dermatologic stage.
    b. neurologic stage.
    c. Pulmonary stage.
    d. rheumatologic stage.

5. The suggestion that insects in their nymphoid stage most readily transmit Lyme disease is derived from the observation that the largest number of cases is reported during:
    a. June and July,
    b. December and January.
    c. September and October.
    d. March and April.

6. The organism that causes Lyme disease is a:
    a. fungus.
    b. protozoa.
    c. spirochete.
    d. virus.

7. Because diagnosis of Lyme disease is complicated due to its early stage mimicking other infections, presumptive diagnosis is frequently based on the presence of:
    a. dermatologic manifestations.
    b. neurologic manifestations.
    c. pulmonary manifestations.
    d. rheumatologic manifestations.

8. The drug of choice for treating the Erythema Migrans stage of Lyme disease is:
    a. chloramphenicol.
    b. metronidazole.
    c. amoxicillin.
    d. ciprofloxin.

9. The best method for removing the insect that carries the organism causing Lyme disease is with:
    a. kerosene
    b. nail polish.
    c. A hot match.
    d. tweezers.

10. The transient condition that follows the initiation of massive dowses of antimicrobial therapy is:
    a. Stevens-Johnson syndrome.
    b. Adams-Stokes syndrome.
    c. Starsky-Hutch syndrome.
    d. Jarisch-Herxheimer syndrome.

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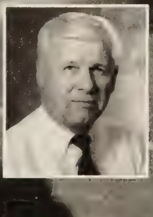

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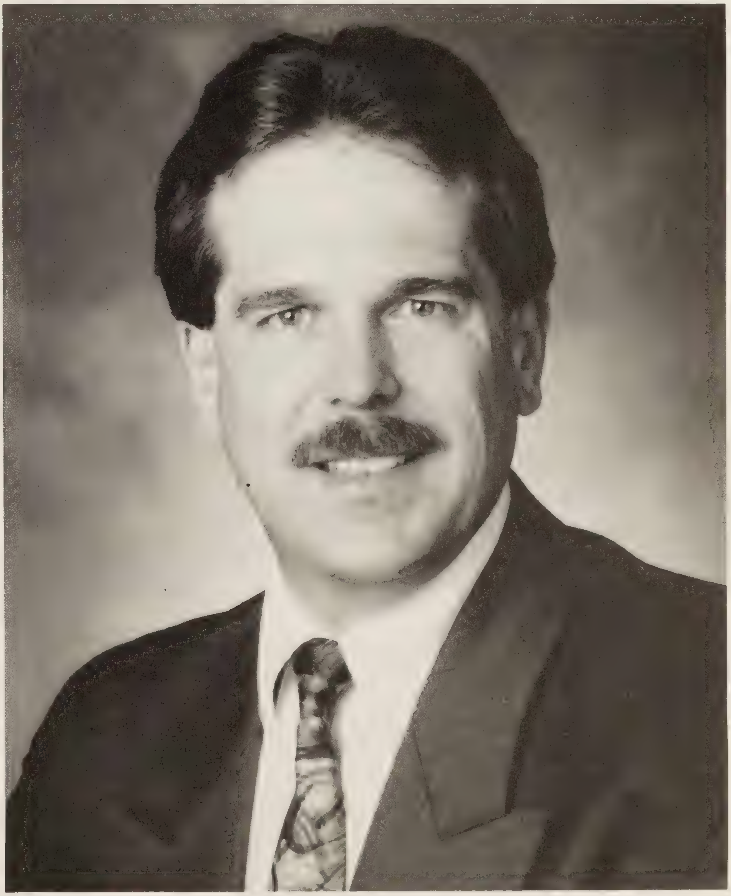

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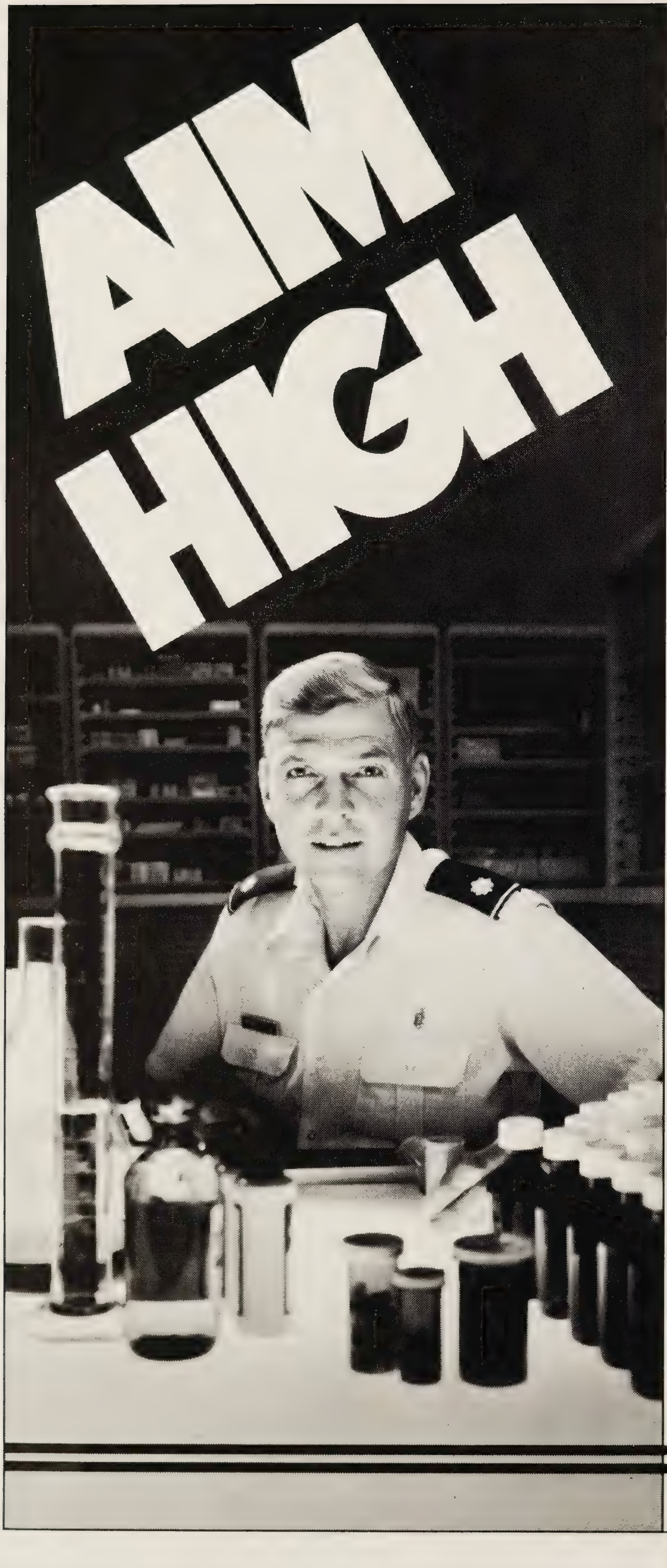

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President's Commentary
A Changing of the Guard

A new year has begun at the Maryland Pharmacists Association. New officers have been elected and new ideas have begun to flow. It sounds like the same ol' MPhA. However, a big change has occurred which brings a sadness to us all. David Miller, our Executive Director for several years, with whom we all became friends with or acquainted with, has resigned from the MPhA to accept a position with Merck & Co., Inc. Our friend will no longer be there as our sounding board for our ideas; he will no longer be there when we need a place to air our frustrations about third party programs, employers, or fellow pharmacists. Dave will no longer be around to give advice about a particular pharmacy problem or pharmacy law.

It seems almost as if we have lost a family member. However, we did not lose a family member, because David is a University of Maryland School of Pharmacy-educated pharmacist, a licensed Maryland pharmacist, and a member of MPhA, which makes him a family member for life. Hopefully, we have gained a sister in this move, by the name of Merck.

David, on behalf of the Officers, Board of Trustees, and members of the Maryland Pharmacists Association, we wish you success and happiness in your new position at Merck.

When a dynasty ends, a new era or dynasty begins in its place. This new era will begin with our new Executive Director, Tracy Baroni. We will need to help her through the transition period by giving her a chance to know us personally and by teaching her how MPhA presently operates. I feel Tracy brings with her a new perspective and energy to the Maryland Pharmacists Association Executive Director position. We have set an extremely energetic course for the MPhA to achieve during the next few years; a course which will require a strong association and good leadership to achieve.

So Tracy, on behalf of the Officers, Board of Trustees, and members of the Maryland Pharmacists Association, we welcome you aboard.

There are new things happening at MPhA. Here are just a few ideas:

☞ Additional features appearing regularly and periodically in the *Maryland Pharmacist.*

☞ Establishment of a "Young Pharmacists Section" for pharmacists practicing for ten years or less.

☞ Establishment of Interest Groups which will focus on projects chosen by the Group - i.e., community-based information programs.

If you have additional suggetions, please contact the MPhA offices at (800) 833 - 7587.

Snake Venom Poisoning

A Medical Emergency

Barry S. Gold, M.D., F.A.C.P.
Medical Consultant, Maryland Poison Center

Snake venom poisoning is a medical emergency. It is a complex poisoning that not only affects the bite site but may affect multiple organ systems, either directly or indirectly. Approximately 45,000 snakebites occur annually in the United States. Only 8,000 of these are from venomous snakes, and only 9 to 15 result in death. The majority of deaths occur in children, the elderly, in those in whom antivenin was not administered, delayed, or given in insufficient amounts, and in members of fundamentalist religious sects who handle poisonous snakes during religious ceremonies. Many victims are young males and about 50% of them are intoxicated and deliberately handling or molesting the snake. Over 90% of bites occur on the extremities, between April and October, with the peak months being July and August.

Only about 25 of the 120 species of snakes native to the United States are poisonous. The majority of poisonous snakebites are caused by members of the family known as Crotalidae or pit vipers, and include rattlesnakes, copperheads and cottonmouths (water moccasins). The coral snake (Elapidae) is the only other native poisonous snake and accounts for less than 1% of all the bites.

Maryland has only two indigenous poisonous snakes: the copperhead and the timber rattlesnake. The copperhead is more common and accounts for the majority of bites. It is found throughout the state, except the central portion of the Eastern shore. The timber rattlesnake is generally found in the western third of the state.

A definitive diagnosis of snakebite poisoning requires identification of the snake along with signs and symptoms of envenomation. Usually, the snake is not available, so an accurate diagnosis and treatment depends on signs and symptoms of snakebite poisoning. Although many people believe that all bites from venomous snakes result in envenomation, this is not true. About 25% of all pit viper bites and 50% of all coral snakebites in the U.S. are "dry" and do not result in envenomation.

Terror is the most common reaction associated with a snakebite. It is important not to mistake autonomic symptoms for systemic symptoms which could lead to unwarranted treatment. The primary local reactions seen in pit viper bites occur within 30 to 60 minutes following the bite. These include fang puncture(s), pain, edema, and erythema or ecchymoses.

Systemic symptoms include nausea, vomiting, perioral paresthesias, fasciculations, and unusual tastes. More severe symptoms include hypotension, dyspnea, and altered mental status. Coagulopathies are frequently seen following bites by rattlesnakes and may result in a DIC-like picture manifested by prolonged prothrombin and partial thromboplastin times, hypofibrinogenemia, thrombocytopenia, and abnormal fibrin split products.

Envenomations are graded as none, minimal, moderate, and severe, based on the presence of local changes, systemic symptoms and signs, and coagulopathies. The severity is based on the most severe symptom, sign, or laboratory result occurring at that time (e.g., a patient with minimal swelling but a systolic BP of 60 mmHg should be graded as severe).

For snake bites and ingestion emergencies call the Maryland Poison Center at (410) 706 - 7701 or (800) 492 - 2414 (in Maryland).

In 1984, a joint committee representing the American Association of Poison Control Centers and the American College of Physicians proposed guidelines for first aid treatment of snake venom poisoning in the United States:

1) Place the victim at rest, provide warmth and reassurance.

2) Immobilize the bite site in a functional position below the heart. Remove rings or constricting items.

3) Transport the victim to the nearest medical facility as soon as possible.

4) The use of ice, tourniquet, incision and suction, and electric shock should be strictly avoided.

The Sawyer's Extractor, a dual chambered negative pressure suction device, has been shown to be effective provided it is applied over the bite site within the first 5 minutes and suction is maintained for 30 to 40 minutes.

Perform a detailed history and physical exam immediately upon arrival at the hospital. Include time, location and conditions surrounding the bite, a description of the snake, underlying medical conditions of the patient, prior history of snakebite, and allergy to horse serum. This should be followed by an initial grading of the bite as none, minimal, moderate or severe. Record circumferential measurements of the bite site every 20 minutes. A baseline CBC, platelet count, electrolytes, BUN, creatinine, creatinine kinase, prothrombin time, partial thromboplastin time, fibrinogen, fibrin split products and urinalysis should be performed. A skin test for hypersensitivity to horse serum should be done only if antivenin is indicated. Equipment for resuscitation should be readily available. **A negative skin test does not preclude a hypersensitivity reaction.** While awaiting the results, the initial dose of antivenin can be reconstituted in the diluent. The patient should be continually reassessed for progression of the envenomation.

Antivenin remains the mainstay of treatment for poisonous snakebites and is most effective when given within the first 4 hours of the bite. Antivenin is unnecessary in most copperhead bites. Tetanus prophylaxis and a broad spectrum antibiotic may be indicated. An analgesic (NOT aspirin) and sedative may be required. The majority of crotalid snake bites and all coral snake bites are subcutaneous and fasciotomy is **contraindicated**. Fasciotomies should be reserved for *rare* subfascial envenomations in which antivenin was delayed or given in insufficient amount. Fasciotomy is indicated ONLY when compartment pressures are measured and exceed 30 mmHg for over one hour.

The most frequently observed complication of treatment is serum sickness, which occurs about 7 to 14 days after antivenin administration. It usually manifests as fever, rash, arthralgias, and lymphadenopathy. Treatment consists of tapering doses of prednisone over 7 to 10 days.

Several bites by exotic snakes that have been illegally imported into the U.S. occur annually. All zoos are required to maintain adequate supplies of antivenin for all venomous snakes on their premises. In the event of a bite, the regional poison center has access to the nearest available source of antivenin and can provide recommendations regarding treatment of bites by exotic snakes. Venomous snakes should *never* be kept as pets.

Call the Maryland Poison Center for all snake bite emergencies. **MP**

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Executive Director's Column - Lights, Camera, Action!

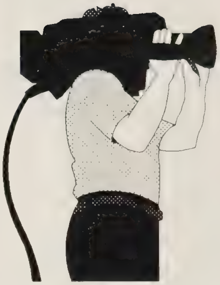
Tracy L. Baroni, R.Ph., J.D.

For those of you who are as yet unaware, the Maryland Pharmacists Association has experienced a theatrical change of scene, of sorts. On May 28, 1996, David Miller exited stage left from the Kelly Memorial Building, never to return as the Executive Director of MPhA, an organization with which he has been intimately involved since 1987.

That was my cue, and I made my official entrance at the Annual Convention in Ocean City on June 15, 1996. Wearing my Convention name badge with the red ribbon bearing the words "Executive Director" attached, I took the opportunity to meet as many members, spouses and guests of the Convention as possible. All the while, repeating my biographical information as if straight out of a play bill.

I attended Duquesne University School of Pharmacy and graduated with a Bachelor of Science in Pharmacy in May, 1987. Two weeks after graduation, I moved to Cockeysville to work for Rite Aid as a student extern. I took my Boards in Maryland, and was a staff pharmacist for Rite Aid until August, 1988. At that time, I went to work for Freedom Drug in Lansdowne, Maryland. In February, 1990, I became a staff pharmacist at University of Maryland Medical Systems, working primarily in the inpatient pediatric/neonatal pharmacy and the I.V. Lab, but also working in adult medicine and picking up a considerable number of night shifts. During this time, I attended University of Baltimore Law School. I graduated from law school in May, 1993 and passed my bar examinations in Pennsylvania and Maryland in July of the same year. In August, 1993, I went to work at Good Samaritan Outpatient Pharmacy. While working at Good Sam, I continued to work some weekends at University, and worked on-call for a home infusion company.

In December, 1994, I accepted a position with the Maryland Board of Pharmacy as the Board's Pharmacist Compliance Officer. As the compliance officer, I was responsible for answering questions on the law for pharmacists and consumers, investigating and reporting disciplinary matters to the Board, and making recommendations on policy matters. I was also intimately involved with the Board's Task Force to Revise the Pharmacy Practice Act, serving on three out of four subcommittees, and writing the report which will accompany the proposed revisions to the offices of legislators in Annapolis.



As you can see, my experience in pharmacy has been varied, and I look forward to continuing my learning curve in my new position. Several people have commented that it must be difficult, switching sides to MPhA after being with the Board. This is as big a mis-cue as I have heard. I view this transition as a lateral move, on the same side of the profession as I have always been - the side which works to enhance the status of the profession among consumers, pharmacists and other health care professionals. The difference is that I now respond to the concerns of you, the members of MPhA.

I encourage members to contact me with suggestions as to how to address the problems facing MPhA and pharmacy today. I look forward to working with students and young pharmacists to increase MPhA membership among these populations. I have spoken to several long-time members of MPhA who have indicated an interest in being actively involved in the activities of MPhA again.

MPhA wants to increase the activity of pharmacists living and practicing in the rural sections of Maryland, and I encourage pharmacists in those areas to contact me with suggestions as to how this can be done. And I will be working with the Board of Trustees and members of MPhA to not only increase MPhA membership in all geographic locations of Maryland, but to increase **active** MPhA membership.

The future of MPhA lies with the pharmacists of Maryland, both MPhA members and nonmembers. The issues facing us are many; the solutions to the issues are varied and complicated. I look forward to the challenge of addressing these issues with and on behalf of MPhA.

With the publication of this issue of *The Maryland Pharmacist*, MPhA lowers the curtain on an extremely successful, long-running Act which included David Miller in the foreground; and, without an intermission, raises the curtain for the beginning of the next Act. Hopefully, many more of you will take this opportunity to become actively involved during the early scenes of what, given the issues and decisions facing MPhA, promises the proverbial "never a dull moment".

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Schering Report XVIII

The Impact on Pharmacy of "No Show" Patients

Jack Robbins, Ph.D., Consultant, Pharmacy Affairs
Schering Laboratories

Phantom, "no show" customers are haunting community pharmacy across America. They consist of two groups: patients who fail to pick up their filled prescriptions, and patients who patronize mail-order pharmacies instead.

Last year, prescriptions filled by pharmacists but never picked up by patients resulted in community drug store losing more than $1 billion in potential sales volume. What's more, mail-order customers express a high degree of satisfaction with their transactions.

These were among the major findings of a new, independent survey commissioned by Schering Laboratories.

Most pharmacists might assume that if people felt sick enough to spend the time and effort to visit a physician and obtain a prescription, they would follow through by picking up the filled prescription and taking their medicine. That's mostly true, but the exceptions are more frequent and have grater impact than the profession might think.

Schering Report XVII, The Phantom Patient and Community Pharmacy Practice, is based on 11,000 telephone interviews conducted nationwide in late summer and early fall of 1995. The new study found that about two percent of the people who brought prescriptions to the pharmacy failed to pick them up. This translates to some 40 million unclaimed prescriptions per year, or well over $1 billion, based on the average prescription cost of about $30.

In addition to these unconsummated sales, community pharmacy suffers other related losses as well. First, there are the costs of filling the original prescription. When that prescription is not claimed, there are the costs of putting the medication back into stock, making sure that the lot numbers and expiration dates match exactly.

But the ultimate price-tag may be even greater. About 20 percent of the patients who had failed to pick up their original prescription said they had to visit the doctor again to get a new prescription to replace the one they failed to pick up. That could add another $200 million or more to the nation's health care bill.

An unclaimed prescription signifies, of course, that the patient has not complied with physician-recommended therapy. While many of the abandoned prescriptions are for short-term illnesses -- from which patients recover, even without medication -- the report took note of some inherent dangers:

Half of unclaimed pres-criptions were for refills, authorized by physicians who believed that their patients really needed the medications. Thirteen percent of the unclaimed prescriptions were for potentially life-threatening disorders such as heart disease and high blood pressure. Failing to take effective maintenance drugs for these diseases can lead to greater morbidity, increased hospital admissions, and a heightened risk of early death.

With respect to the types of people who leave their prescription unclaimed, the report profiled them as follows:

- They are comparatively young. Half are under 35.
- They are more likely than the average patient to be female.
- About 13 percent are retired (compared to about 20 percent who are retired in the general population).
- About 58 percent are homeowners (compared to 67 percent in the general population).
- About 36 percent are non-white (compared to 19 percent in the general population).

The Schering report also included these significant findings:

℞ Unclaimed prescriptions were about evenly divided between new prescriptions and refills. But more women than men left new prescriptions unclaimed.

℞ Most unclaimed prescriptions were for respiratory, allergic, and gynecological problems - conditions more prevalent among younger adults. A smaller number of prescriptions were for heart and blood pressure disorders that usually afflict older people.

℞ Unclaimed prescriptions were almost twice as likely to have been phoned in, rather than brought in.

As to why patients fail to pick up their prescriptions, the report cited the two main explanations given by survey participants: (1) that they had recovered from the condition (39 percent), (2) that they "just forgot" (38 percent). Other reasons given were:

- They already had a similar medicine at home (35 percent).

- They didn't feel they needed the medicine (34 percent).

- They didn't like to take medicine (32 percent).

- The cost was too high (31 percent).

- Picking up the medicine was not convenient (29 percent).

Commenting on this litany of excuses, the report calls attention to the relatively younger age of patients who fail to claim their prescriptions. Three-quarters of the no-shows are between the ages 18 and 24. It is precisely this age group that has the highest incidence -- among adults -- of short-term, self-limiting diseases. Thus, the explanation of many that they had recovered without the aid of medicine has the ring of truth.

The other major reason -- forgetfulness -- is harder to accept at face value. It's a rule of thumb in psychology that people tend to remember what interests them. But they don't always realize what is in their best interest, especially their long-term interest. Indeed, researchers of health behavior often report that younger adults are much more indifferent to their health than are older individuals.

Most young people are so well-endowed with health that many don't see much point in conserving it. One usually thinks that older people are more forgetful. But in Schering's study, it was the younger folks who forgot most often -- a relative 80 percent more often than the senior citizens.

Unfortunately, the study also suggested that pharmacists, in general, have not done very much to reduce this problem. The great majority of people -- 77 percent -- who have left a prescription unclaimed maintain that the pharmacy never even called to remind them to pick up the medication.

What, if anything, can pharmacies do to reduce the number of unclaimed prescriptions? The study had these suggestions:

Pharmacists could do more to remind patients that they have a prescription waiting for them. A phone call, repeated weekly if necessary, would reduce the rate of abandonment -- especially if patients were gently reminded of the importance of complying with therapy.

The prescribing physician might become a willing and persuasive ally. In these days of managed care and disease management, a lower level of morbidity among patients is definitely to the financial advantage of doctors.

It's important for the pharmacist always to obtain the patient's telephone number when a prescription is phoned in or brought in.

A word or two from the pharmacist about the need for compliance when the patient delivers the written prescription to the drug store might be helpful.

Turning to the other major theme of the study -- the impact of mail order prescriptions -- the report observed that there are few issues that unleash as much outrage among community pharmacists as this topic. However, medicine by mail is actually an American institution, as traditional as apple pie.

Sears, Roebuck and Company, for example, began selling OTCs by mail through its catalogs a century ago. The Veterans Administration started mailing prescription drugs to entitled veterans after World War II, and by 1994 was shipping some 38 million prescriptions a year by this method. In the same year, the American Association of Retired Persons was already mailing out close to 10 million prescriptions annually.

The virtues of lower cost and greater convenience provided are still treasured by many American consumers, and have fueled the spectacular ascent of mail order drugs.

Figures compiled by IMS Americas, a leading research company, showed that mail order pharmacy out distanced all other segments in market share growth in six of the last eight years. While more than 7,000 independent pharmacies closed form 1990 to 1994, mail order outlets -- each filling millions of prescriptions a year -- grew from 109 in 1990 to 168 in 1994.

The rise of mail order pharmacy flattened out that year, however. For the first time in over 15 years, its market share did not increase. During the first nine months of 1995, while mail order sales grew by $1.5 billion, its market share declined to just over 7 percent.

But even in this period of lowered growth, mail order pharmacy is thriving. In 1994, for instance, the increase in sales per mail order outlet was $3.5 million.

So far, mail order pharmacy is making only marginal inroads on total retail pharmacy sales. The survey showed that only 7 percent of the people interviewed -- or, by projection, about 13 million people -- had made a mail order pharmacy purchase in the past year. Now that mail order growth appears to have plateaued, the time may have come for hard thinking about how to recover some ground lost in the last decade.

The study showed that satisfaction is well nigh universal among customers of mail order pharmacies. Eighty-seven percent of mail order users are extremely satisfied or very satisfied with the fulfillment of their prescription.

The Schering Report provided a statistical overview of these mail order customers:

> Nearly half (46 percent) are 55 years of age or older, compared to only 29 percent of the general population.
>
> Fifty-seven percent are female, compared to 52 percent of the general population.
>
> Sixty-seven percent are married, compared to 55 percent of the general population.
>
> Only about half are employed, full or part-time, compared with almost two-thirds of the U.S. population.
>
> Thirty-five percent are retired, compared to the general population average of 20 percent.
>
> Their typical yearly income is $40,000 -- $5,000 over the population average.
>
> Eighty-four percent own their homes, compared to the national level of 60 percent.
>
> About 87 percent are white, compared to 79 percent of the general population.

Nearly all prescriptions (90 percent) sent to mail order pharmacies are for refills for maintenance drugs, intended to treat chronic disorders. By contrast, only 46 percent of the prescriptions brought in to community pharmacies for are for refills of maintenance drugs. Almost 75 percent of mail order customers queried believed the prices they paid were below those that a retail drug store would charge.

Is there a strategy which conventional drug stores might adopt to recover some of the maintenance prescription business lost to mail order pharmacies?

The survey found that the older the individual, the more importance he or she gave to the interpersonal aspects of the prescription. Those approaching or over 60 years of age are much more likely to cite trust in the pharmacist, receiving good advice, and the feeling that the pharmacist cares personally about the patient's well being.

The majority of mail order customers would, in short, be responsive to a strategy that stressed the availability of supportive personal interaction between pharmacist and patient at the community pharmacy. If community pharmacy is to survive and flourish, all elements of pharmacy practice, whether independent, chain, HMO, food store or mass merchandiser, need to make personal patient-pharmacist interaction more meaningful and helpful to the patient. **MP**

Schering Laboratories is the U.S. prescription pharmaceutical marketing arm of Schering-Plough Corporation of Madison, NJ, a research-based company engaged in the discovery, development, manufacturing and marketing of pharmaceutical and health care products worldwide. Each year, Schering sponsors a profession wide survey of issues facing pharmacists.

DISCOVER CRUISING

The Maryland Pharmacists Association

presents the

GRANDEUR OF THE SEAS

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January 25-February 1, 1997

She is called the *Grandeur of the Seas.* And it only takes a moment to see why. For she's built to exceed every convention of cruising. And next winter she'11 be the newest ship in the Caribbean. With more acres of shining glass, more open spaces, more private verandas. Her beauty will be unparalleled. Come aboard for the sweeping staircases, glass lined promenades and an entire crew with nothing in mind but your comfort. Explore her spacious theatre, her pool and cafe protected by a glass canopy. But as busy as you'll be, we're sure you'll find time for this realization: that this ship is *grandeur.* During the cruise you'll visit two private beaches plus St. Thomas and San Juan. But think of the ship as a destination in itself. You will be extremely pleased. And for those who wish to stay longer in Florida, either before or after the cruise, arrangements can be made. There are only a limited number of cabins available in each category. Don't be left at the dock! Send in your reservation today.

A Continuing Education Seminar will be held on-board (8 credits).

Category	Deck / Description	Brochure Rate	Group Rate
C	**Bridge Deck/Commodore Deck** - outside suite, two lower beds, private veranda, sitting area w/sofa bed, refrigerator, bathtub.	$2329	$1239
D	**Commodore Deck** - deluxe outside stateroom, two lower beds, private veranda, sitting area w/sofa bed, refrigerator	$2119	$1059
H	**"A" Deck** - larger outside stateroom, two lower beds, sitting area w/sofa.	$1899	$ 944
L	**Main Deck** - larger inside stateroom, two lower beds, sitting area w/sofa.	$1749	$ 879
M	**"A" Deck/"B" Deck** - standard inside stateroom, two lower beds, sitting area w/sofa.	$1699	$ 857

Airfare add-on from BWI is $279 per person.

Port taxes, departure taxes, custom fees are $114.50 additional. All rates are per person, double occupancy. Pre-post-extensions are available.

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GRANDEUR OF THE SEAS — ITINERARY

Day	Port of Call	Arrive	Depart
Sat.	*Miami, Florida*		*5:00 pm*
Sun.	*At Sea*		
Mon.	*Labadee, Haiti*	*8:00 am*	*5:00 pm*
Tue.	*San Juan, Puerto Rico*	*12:30 pm*	
Wed.	*San Juan, Puerto Rico*		*2:00 am*
	St. Thomas, USVI	*7:00 am*	*5:00 pm*
Thu.	*At Sea*		
Fri.	*Cococay, Bahamas*	*10:30 am*	*6:00 pm*
Sat.	*Miami, Florida*	*8:30 am*	

Only 25 Cabins Available *Book Early!*

Reservations and Cancellations: Deposit of $200 per person required to secure a reservation. Payment in full due November 15, 1996. Cancellations received prior to November 6 will receive full refund less $75 per person bookkeeping charge. Cancellation received prior to December 6, 1996, receive full refund less $200 per person. Cancellations received prior to December 23 forfeit 55% of cruise fare. After December 23, 1996, no refund. **Group cancellation terms differ from individual cancellation terms. All cancellations must be in writing. CANCELLATION INSURANCE IS AVAILABLE AND HIGHLY RECOMMENDED**

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Reservation Form

Enclosed is my deposit in the amount of $________ ($200 per person) for #________ persons on the Grandeur of the Seas Cruise.

Names (1)________________________________

(2) ________________________________

(full name as it appears on passport/legal documents)

Address ________________________________

____

Home Phone________________ Office Phone________________

I have read and understand the Reservations and Cancellation policy. ____________ (initial)

Cabin Category: ______ ☐ **Cruise Only** ☐ **Cruise with Air**

PROOF OF CITIZENSHIP IS REQUIRED FOR THIS CRUISE.

Make check payable and mail with this reservation form to:

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October 12-16, 1996

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NARD
98th Annual Convention and Trade Exposition

October 12-16, 1996
New Orleans, Louisiana
Registration Made Easy!

- By fax: Dial NARD's fax machine 24 hours a day at 703-683-3619 (credit cards only)
- By mail: NARD, Conventions and Meetings Dept., 205 Daingerfield Road, Alexandria, VA 22314
- By phone: Call NARD at 800-544-7447 or 703-683-8200 (credit cards only)

Complete this form and return it to NARD with your check or charge authorization for the full amount of registration fees. **Your registration cannot be processed unless all information is provided.**

If cancellation is necessary, your conference fee, minus a $35 per person processing fee, will be refunded. Requests for refunds must be in writing. **Refunds will not be processed for cancellations made after October 12, 1996, or for no-shows.**

Questions?
Call 800-544-7447

Are you a

- ○ 1st time convention attendee?
- ○ New NARD member?
- ○ NARD member since at least 1971?

1.

NARD Membership Number   Nickname

Name (Check one) ○ R.Ph. ○ P.D. ○ Student

Pharmacy Name

Business Address

City   State   ZIP

Business/ Phone   FAX

Spouse/Guest (non-pharmacist) Registration
Note: not eligible for C.E. credit

Name

2. Additional Team Member(s) Registration

Please complete a separate convention and housing registration form for each team member.

Attention Team Members!
Please fill in the name of your sponsoring team leader:

Active Member   Member #

○ Team Member—payment enclosed
○ Team Member—Registration fees paid by Team Leader

3. Registration Fees:

	Early Registration	After 9-1-96	Weekend Only
○ NARD Active Member	$260	$310	$155
○ 1st Team Member	$210	$260	$130
○ 2nd Team Member	$160	$210	$105
○ NARD Corporate Member	$260	$310	N/A
○ Spouse/Guest (non-pharmacist)	$100	$125	$35
○ Nonmember*	$420	$470	$210
○ Non-exhibiting Company Rep.	$515	$515	N/A
○ Pharmacy Student	**FREE**	**FREE**	**FREE**

* $160 can be applied to new membership in NARD.
○ Check here if you want to join NARD.

I am attending
○ Weekend only   ○ Entire convention

One Day Registration Fee
○ Member $105   ○ Nonmember $155

Which day will you be attending?______________

4. Special Events:

Please indicate your attendance at the following special events and figure the cost into your grand total.

○ Basic Diabetes Care Program	$120
○ Advanced Diabetes Care Program	$120
○ Golf Tournament	$140
○ Tennis Tournament	$40
○ CMO-Ready: Advanced Orthoses Workshop	$250
○ Fun Run/Walk	FREE
○ Contemporary Issues in Diabetes Care	$25
○ Partners in Pharmacy Breakfast	$20
○ Respiratory Care Program	$120
○ Pharmacy Management Program	$120
○ Pharmacist Care Skills Program	$120
○ Cardiovascular Care Program	$120

5. Payment:

Total fees from Sections 3 and 4 for your grand total.

My grand total is:______________
○ Enclosed is my check
○ Charge my:
○ American Express   ○ MasterCard   ○ Visa

Card Number   Expiration Date

Signature

HOUSING RESERVATION

We cannot reserve housing without a paid convention registration.

Please read all instructions before completing the housing application.

Hotel reservations can be made through the NARD Housing Bureau only.

Reservations will be processed on a first-come, first-served basis. **To secure room, reservations must be received prior to September 9, 1996.** After this date, requests will be handled on a space-available basis. A deposit equal to one night's stay is required to hold each reservation.

NARD will acknowledge receipt of your reservation by mail. This is NOT a confirmation. A confirmation will be forwarded directly by the hotel (please allow four weeks). Changes in arrival/departure dates, accommodations, and cancellations are to be made through the NARD Housing Bureau. After September 1, 1995, notify the hotel directly.

1. Participating Hotels and Rates

Check box next to your first choice.

Hotel
○ Single   ○ Double

○ New Orleans Marriott	$162
○ New Orleans Sheraton	$185

Note: An 11 percent sales tax plus a $3 occupancy tax per room, per night will be added.

2.

Name

Sharing room with

Arrival Date

Departure Date

Number in Party

3. Special Requests:

○ Non-smoking, if available
○ Low floor
○ King-sized bed
○ If you have a disability that requires special consideration, please check here and attach a written description of your needs.

Your New Orleans accommodations can be reserved using a credit card only. One night's deposit is required to make the reservation. **Your housing reservation will not be processed without a paid convention registration.**

4. Payment

○ Check here if you want to use the same credit card you used for your convention registration fees.

○ Check here if you are using a different credit card, and fill out the information below.

○ Visa   ○ MasterCard   ○ American Express

Name on Card

Card #

Expiration Date

Signature

For Travel Arrangements
Call Atlas Travel at
800-292-2238, Monday-Friday,
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Annual Report

Maryland State Board of Pharmacy

Dorothy Levi, P.D., Secretary

In compliance with the provisions as set forth in the Health Occupations Article Section 12-205 of the Annotated Code of Maryland, this report is submitted to the Honorable Parris N. Glendening, Governor of Maryland, the Secretary of Department of Health and Mental Hygiene, Martin P. Wasserman M.D., J.D. and to the Maryland Pharmacists Association. This is the ninety-second report to the Governor and Secretary and the thirteenth report to the Association. The report covers the activities of the Maryland Board of Pharmacy for the period May 1, 1995 to April 30, 1996. This report is also being submitted to the McKeldin Library of the University of Maryland, the Enoch Pratt Free Library, the Department of Legislative Reference, the Hall ofPRecords and the State Library.

Meetings

During the year the Board held twelve Board meetings to discuss all issues relevant to the pharmacy profession.

Officers and Members

The Board consists of the following officers and commissioners: George Voxakis, President; Dorothy Levi, Secretary; Barbara J. Faltz Jackson, Robert J. Kabik, Melvin Rubin, Theodore S. Litwin, George Voxakis, David Russo, and W. Irving Lottier, Commissioners. All of the officers and commissioners are registered pharmacists in the State of Maryland with the exception of Mr. Litwin and Ms. Jackson who are consumer (public) members of the Board.

Personnel

The staff consists of Norene Pease, Executive Director, Tracy Baroni, Pharmacist Compliance Officer, Tamarra Banks, Network Specialist, David Oliver, Secretary to the Pharmacist Compliance Officer, Shawnette Fleet, Licensing Clerk, and Doris Thomas, Fiscal Aide. The position of Secretary to the Executive Director has been vacant and/or filled by contractual persons since November 1996. This position will be filled by Monique Cheatam effective May 22, 1996.

Examinations

The Board conducted examinations for licensure of pharmacists twice during the year. The examinations were held at the University of Maryland School of Pharmacy on June 27, 28, and 29 1995 and at the University of Maryland School of Social Work on September 19 and 20, 1995.

The applicants who were examined in June of 1995 were licensed in August, 1995. There were one hundred forty-eight applicants for the Board examination in June 1995. One hundred eighteen passed both the theoretical and practical portions of the examination and were licensed. Thirty candidates failed the examination.

There were sixty-one applicants for the Board examination in September, 1995 (F.Y. 1996). Forty- seven passed both the theoretical and practical portions of the examination and were licensed. Fourteen candidates failed the examination.

Data relative to the June 1996 examination will be given in the next Annual Report.

The pharmacist licensure examination is given in three parts consisting of the following:

Part I - NABPLEX
Part II - Pharmacy Law
Part III - Laboratory

The NABPLEX is obtained from the National Association of Boards of Pharmacy. The Pharmacy Law Exam and the Laboratory Exam are compiled by members of the Board. The pharmacy law examination requires examinees to respond according to what a pharmacist practicing in Maryland must do in a particular situation in order to comply with Maryland and Federal law. The Laboratory Examination requires each candidate to compound and label four prescriptions per applicant.

Each of the three parts stands on its own for grading purposes. An examinee need only retake the section(s) failed. The passing grade for each section is 75 percent.

Table One the number of pharmacists who were licensed by examination during the past ten years.

As in the past, many pharmacists applied for reciprocal licensure in Maryland in order to accept positions with employers or in order to become self-employed as pharmacists in Maryland.

In all cases, an applicant for reciprocal licensure must appear for a personal interview. The entire Board must act on whether or not to grant licensure to such applicants, who must sign an agreement to comply with Maryland's laws pertaining to drugs and pharmacy.

Table Two shows the number of pharmacists granted Maryland licensure by reciprocity and the number licensed in Maryland who were certified to be licensed in another state by reciprocity during the past ten years.

Year	*Number of Pharmacists*
1984-1985	92
1985-1986	109
1986-1987	105
1987-1988	121
1988-1989	135
1989-1990	167
1990-1991	156
1991-1992	149
1992-1993	145
1993-1994	199
1994-1995	199
1995-1996	165

Table One

Pharmacists Licensed by Reciprocity or Certification

Fiscal Year	**Reciprocity**	**Certification**
1984-1985	148	54
1985-1986	191	70
1986-1987	206	75
1987-1988	197	57
1988-1989	228	86
1989-1990	187	103
1990-1991	212	98
1991-1992	178	86
1992-1993	192	119
1993-1994	190	88
1994-1995	183	52
1995-1996	229	105
TOTAL	2,460	993

Table Two

Permits and Licenses
As of April 30, 1996, seventy new permits to operate a pharmacy were issued. The number of permits per county are: Anne Arundel (5), Baltimore (20), Charles (2), Howard (4), Prince Georges (2), Somerset (1), Washington (6), and Baltimore City (30).

In June, 1987, regulations were promulgated under COMAR, Title 10, Subtitle 34, Chapter 17, allowing waiver of full service requirements for recognized pharmaceutical specialties. As of April 30, 1996, the Board issued twenty-seven (27) new pharmacy waiver permits as follows: eight (8) in Baltimore County, one (1) in Anne Arundel County, zero (0) in Howard County, zero (0) in Montgomery County, zero (0) in Prince Georges County, and zero (0) in Wicomico County, three (3) Allegheny County, zero (0) Garrett County, one (1) Frederick County and fourteen (14) in Baltimore City.

New permits to manufacture drugs, medicines, toilet articles, dentifrices, or cosmetics were issued to ten (10) entities during the year.

The Board issued ninety-two (92) new permits to distribute prescription drugs during the year.

The total number of establishments licensed through the State of Maryland is 1,581 and the total number of licensed pharmacists is 6,964 as of April 30, 1996.

Legislation
The following bills which affect pharmacy either directly or indirectly were enacted by the 1996 General Assembly. These bills must be signed by the Governor to become effective.

SB 359 and HB 1004 - Health Occupations - State Board of Pharmacy
The Bill authorizes the Board to change the renewal dates for pharmacist licenses issued. The purpose of the Bill is to enable the Board to renew pharmacists licenses during the pharmacists birth month, therefore, balancing work flow during the year and reducing errors associated with processing a high volume of licenses within a two month period. The Bill further authorizes the Board to enter into agreements with other states to grant reciprocal licensure to pharmacists under certain conditions. The Bill was passed by the Legislature.

SB 360 and HB 1003 - Licensure - Oral Competency Exams
The Bill authorizes the Board of Pharmacy to require that individuals applying for licensure as a pharmacist in the State pass a test of Oral English competency prior to licensure.
The Bill was passed by the Legislature.

Cooperative Activities
The Board maintained cooperative activities with the Division of Drug Control; Licensing and Certification; the State Department of Health and Mental Hygiene; the University of Maryland School of Pharmacy; the Maryland Pharmacists Association; the Maryland Society of Health System Pharmacists; the Maryland Association of Chain Drug Stores; the Maryland Chapter of the American Society of Consultant Pharmacists; City, County and State Police; the National Association of Boards of Pharmacy; and all Pharmacy Boards and Schools of Pharmacy throughout the country.

Disciplinary Activities
The Board of Pharmacy receives complaints from the public concerning problems with the Board's licensees. Other complaints were received from the Division of Drug Control, Medical Assistance Compliance Administration, Licensing and Certification, State of Maryland Courts and other state boards of pharmacy. The wide range of complaints varied in severity. A total of 73 complaints were reviewed by the Board of Pharmacy. Listed below are statistics concerning the types of complaints for the period of May 1, 1995 through April 30, 1996:

- mislabeled prescriptions
  4 complaints
- incorrect drug dispensed
  31 complaints
- shortages of medication
  5 complaints
- communication
  2 complaints
- prescription not dispensed
  3 complaints
- Board taken action by another State
  5 complaints
- inconsistent with professional standard
  17 complaints
- continuing Education
  4 complaints
- Impaired or chemical dependency
  2 complaints

During the period of FY 1995, eighteen (18) disciplinary orders were executed by the Board and became available as public information. These orders covered seventeen (17) pharmacists and one pharmacy.
Pharmacist actions included: one emergency suspension, seven suspensions with immediate stay and probation, eight full reinstatements, two surrender of licenses, and one revocation. Pharmacy actions included one emergency suspension.

During this period, the Board voted charges for violation of pharmacy law against 23 pharmacists and one pharmacy. Twenty of these twenty-four cases have been concluded (included in the above statistics) and three are outstanding.

The Board has four additional outstanding cases from the previous year which have not been concluded. Of these, three pharmacists' licenses are currently suspended on an emergency basis pending final resolution. The Board has voted charges for formal action against the one remaining case.

Some pharmacists were convicted of violating more than one provision of the Pharmacy Practice Act. Listed below are the types of violations according to the section of 12-313(b) of the Health Occupations Article and the number of pharmacists convicted of each:

2. Fraudulently or deceptively uses a license; 2 violations.
4. Provides professional services while: (I) Under the influence of alcohol; or (ii) Using any narcotic or controlled dangerous substance, as defined in Article 27 of the Code, or other drug that is in excess of therapeutic amounts without valid medical indication; 1 violation.
6. Willfully makes or files a false report of record as part of practicing pharmacy; 1 violation.
14. Without first having received a written or oral prescription for the drug from an authorized prescriber, dispenses any drug for which a prescription is required; 3 violations.
20. Is professionally, physically, or mentally incompetent; 2 violations.
23. Is disciplined by a licensing or disciplinary authority of any other state or country or convicted or disciplined by a court of any state or country for an act that would be grounds for disciplinary action under the Board's disciplinary statutes; 1 violation.
24. Violates any rule of regulation adopted by the Board; 1 violation

Data Processing

Fiscal years 1995 and 1996 are the last phases in the Board of Pharmacy's five year office automation plans. The purchase of personal computers and a local area network began this process in 1994. The focus of the five year plan was to provide pharmacists, Board staff, other organizations, and the public with timely and accurate information. In the past year the Board has increased its communication capabilities with the use of electronic mail and the Internet. The Board of Pharmacy can provide licensure information for other State agencies and associations within 8 hours, previously this process required 7 days. Other health licensing Boards will be obtaining local area networks and the Board of Pharmacy intends to connect with these systems to share information and resources.

The Board can communicate electronically with the Department and any other agency with electronic mail capabilities. The Board has installed computers at the remote locations of the Board's counsel and at the Division of Drug Control, providing them access to the Board's local area network. The National Association of Boards of Pharmacy (NABP) has developed and installed at most State Boards the Electronic Licensure Transfer Program (ELTP). This system was introduced in February 1996 for the purpose of providing State Boards access to the national database of licensed pharmacists. Previously, those pharmacists wishing to practice pharmacy in another State were required to mail an application to several places to verify information. With the ELTP system, applications mailed to NABP are inputted into the system and electronic mail is instantly sent to the State of transfer. Pharmacists may also initiate the transfer of their licensure to another State from their own computers.

By June 30, 1996, the Board of Pharmacy will implement an optical computerized scanning system to reduce the need for paper files, improve turn around time for renewing licenses, enhancing response time for other informational requests and reducing the potential for errors in all aspects of Board operations. Other Boards are planning to utilize the scanning technology acquired by the Board of Pharmacy.

Finances

Effective July 1, 1995 pharmacists licensed by the Board were given a reduced pharmacist licensure renewal fee. Initially the fee was $130, it was reduced to $95 to be paid every two years. This and other fee adjustments will effect overall annual revenues as well as reducing carryover revenue.

A budget amendment to utilize carryover funding to immediately address the need for administrative prosecutors was approved. The amendment also included funds for the Board of Pharmacy's optical scanning system. The scanning system was originally budgeted in fiscal year 1995 however, the acquisition process extended into fiscal year 1996. This made it necessary to retrieve those funds from 1995 carryover.

Financial Statement

The Board of Pharmacy had revenues of $839,793 in 1994 and $893,621 in 1995. The Board's expenditures were $511,849 for 1994 and in 1995 were $461,535. The Board did not spend it's total appropriation in FY94 or FY95, thus increasing carryover. Revenues and expenditures for fiscal year 1996 are projected at $720,040 and $769,876 respectively. The Board's goal is to spend the amount allocated in the appropriation made by the General Assembly. This is the first year since the Board became special funded that it is projected to spend the total appropriation. The Board's expenditures exceed revenues in FY96 in order to reduce carryover.

Regulations

During 1995, as required by Law, the Board reviewed all of its regulations. The results of that review are listed below:

The Board promulgated the following regulations, either amended, repealed, or new:

10.34.03 Inpatient Institutional Pharmacy (new)

10.34.18 Continuing Education for Pharmacists (amended)

10.34.20 Prescription Orders Transmitted by Facsimile Devices (amended)

The Board has the following amended, new, or repealed regulations in progress:

10.34.23 - Long Term Care Facilities (new)

The program has hired a full time Regulations and Legislation Specialist who is currently tracking and assuring that 55 sets of regulations are promulgated in an efficient and timely manner. The Boards and Commission review and write positions on several hundred proposed pieces of legislation each Session.

Continuing Education

Continuing education program (C.E.) approval is requested monthly by program sponsors and program attendees for programs not accepted by the Maryland regulations. Requests are approved monthly or returned to the sponsor or attendees for additional information. The 1995 license renewal process resulted in 13 extensions to obtain the required continuing education credits.

One Board approved Continuing Education Provider Application was approved for January 1, 1996, to December 31, 1997. Continuing Education requirements are regularly included in disciplinary cases and reviewed for compliance throughout the year. The 1994 Continuing Education Audit is due to be completed by November 1, 1996, when all pharmacists not in compliance with the audit will satisfy their agreement with the Board.

The 1995 Continuing Education Audit began in February 1996 and is currently in progress. All pharmacists notified of their selection as an audited licensee have not responded; the Board will review this situation.

Two new Board members, one pharmacist, and one consumer member, will be new members of the Continuing Education Task Force. The consumer member has begun the orientation process. A soon-to-be appointed pharmacist member will join the Task force at the time of appointment.

With the impending arrival of scanning equipment, it is very likely that the Board will begin a 100% audit of continuing education in the near future.

The Continuing Education requirement for licensure will be modified from October 1, 1996, through December 31, 1999 in order to accommodate the new license renewal system based on each pharmacist's birth month. The audit process will remain the same. All pharmacists renewing from January through December of a calendar year will be audited in January or February of the following year.

The Board voted to consider becoming a provider of C.E. programs to Maryland licensees. It is anticipated that the first Board-sponsored program will be presented in 1996.

Secretary-Treasurer's Message

The Board will be going through a transition period over the next few months. It began with my assumption of the Secretary-Treasurer responsibilities in April. We are anticipating the arrival of the person hired to fill the lead secretary position, and we will have three new Board members soon.

Concluding their term of five years on the Board are Melvin Rubin and Robert Kabik, and Theodore Litwin, one of our consumer members, will be leaving after ten years on the Board. Mr. Rubin has been the Board's Secretary-Treasurer for two years, and has participated on the following Committees - Licensing, Pharmacy Practice, Budget/Finance, Legislative and Disciplinary; on the following task forces: Pharmacists' Rehabilitation Committee (PRC), Acute Care, Long-Term Care, and Revision of Title 12; and as a member of the Editorial Review Board and Council of Boards and Commissions. Mr. Kabik has been Chairman of the Pharmacy Practice Committee, and has participated on the following Committees: Disciplinary, Legislative; and on the following task forces: PRC and Revision of Title 12; and as a member of the Editorial Review Board. Mr. Litwin has been a member of the Licensing and Disciplinary Committees and the Editorial Review Board. He has been our resource on Quality Assurance and has overseen the PEP students and preceptors. It is easy to see how much all of these Board members have contributed of their knowledge, experience, and time to the work and successes of the Board. Their years of public service are greatly appreciated. Thanks to all of you!

During the year addressed in this annual report, the Board has dealt with the usual responsibilities: Board examinations in June and September; pharmacist license renewals in July, August, and September; establishment license renewals in December; legislation from January to April, and Continuing Education extensions in October and audit in February.

Regulations for long-term care facilities were completed and changes to the regulation governing transmission of prescriptions via facsimile will be made to include the electronic transmission of prescription information and will soon be completed.

A special project this year has been the Title 12 Task Force to Revise the Pharmacy Practice Act. This Task Force consists of representatives from all aspects of our profession, and is charged with reviewing all aspects of pharmacy practice. A final report from the Task Force was given at the Board meeting in May, 1996.

New areas of the Board's involvement include monthly pharmacist license renewals, implementing a written reciprocity examination, requiring oral competency for licensure and utilizing a National Association Boards of Pharmacy - prepared Federal and State Law Examination.

The Board has provided financial assistance to the PRC for the second year.

Discussions will continue on pharmacy security, composition of the Laboratory Examination, Board - sponsored C.E. programs, and dispensing by other health care providers.

During this year the Board has expanded its Public Agenda and is discussing the majority of its business during the Public Meeting. There has been consistent representation from many pharmacy organizations at the Public meetings, including Maryland Pharmacists' Association, Maryland Society of Health-System Pharmacists, Maryland Pharmaceutical Society, University of Maryland School of Pharmacy, and the Division of Drug Control. This interaction is very beneficial to the Board, as well as all the organizations that participate. The Board also appreciates the space given to it by the Maryland Pharmacist Association in the "Association's Journal" for articles from the Board and for a display at the Annual Convention.

The past year has been a busy one, with numerous accomplishments. Current work will continue into next year. The Board encourages your participation, questions, comments, and suggestions. **MP**

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Litigation Update

Restricted Practice

David B. Brushwood, R.Ph., J.D.

A United States Circuit Court of Appeals has recently upheld a decision by the Drug Enforcement Administration (DEA) to deny a request for a waiver of a restriction on the employment of a pharmacist who had previously been convicted of felony related to controlled substances.

The pharmacist seeking employment had become licensed as a pharmacist in Michigan in 1964. In 1987, he was one of 30 pharmacists who were indicted for conspiracy to defraud insurance companies and divert controlled substances for profit. He pled guilty to one count of racketeering activity (specifically, to instances of distribution of Preludin, outside the course of legitimate medical practice). Pursuant to his plea, he agreed to relinquish his pharmacy licensed. He received a four year prison sentence. In 1993, the Michigan State Board of Pharmacy reinstated his pharmacy license, on the condition that he practice pharmacy under the personal supervision of a licensed pharmacist for 6 months, followed with one year of general supervision by a licensed pharmacist.

The pharmacist was offered employment by a prospective employer, who discovered that he could not hire the pharmacist due to a DEA regulation that provides a registrant shall not employ any person who has been convicted of a felony relating to controlled substances. The DEA has a practice of waiving this provision, under certain circumstances, but refused to waive the provision in this case. the pharmacist and the prospective employer sued the DEA, contending that the agency should grant a waiver and permit the pharmacist to be employed.

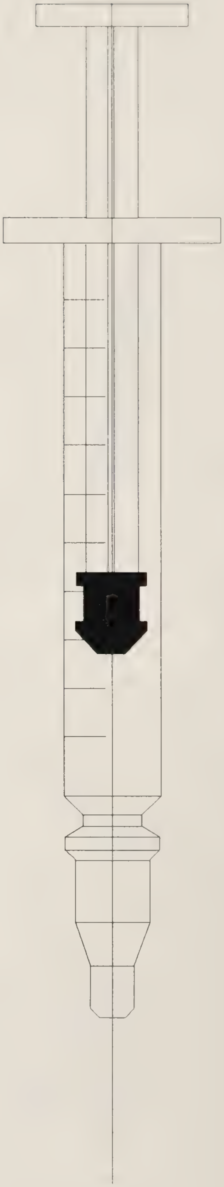
On review, the court disagreed with the petitioner's contention that there was insufficient evidence to support denial of a waiver. The court pointed to the extensive nature of the illegal activities in which the pharmacist had engaged, and to the inadequacy of the prospective employer's plan, which would leave the pharmacy in charge of the pharmacist in the event of vacations by store staff, and entrust to pharmacy technicians the responsibility to "watch" the pharmacist.

The court disagreed with the petitioners that the DEA had promulgated an unconstitutionally vague waiver regulation. The court cited a DEA document that stated the factors determinative of granting of a waiver to be: (1) the prospective employer's understanding of the circumstances of the prospective employee's drug-related felonies, and (2) the prospective employer's plan to supervise the prospective employee's access to controlled substances. These factors are clear, thus the wavier provision is not vague. While not precluding the possibility of future approval of a waiver, the court upheld the current denial of a waiver.

Based on Bzdzuich v. United States Drug Enforcement Administration, 1996 U.S. App. Lexis 2622 (February 22, 1996). Copyright 1996, David B. Brushwood. All Rights Reserved. Reprinted from Dickinson's Pharmacy, March 1996.

A Resurgence in Isoniazid Poisoning

Cathleen Clancy, M.D., ABMT,
Maryland Poison Center



CASE: A 30-year-old woman ingested 20 (300 mg) isoniazid tablets in a suicide attempt. She presented 30 minutes after ingestion and was asymptomatic. Therapy included gastric lavage and activated charcoal. Two hours after ingestion she had the first of multiple seizures. The hospital did not have pyridoxine in stock. Three hours after ingestion she was intubated with a blood pressure of 104/60 mmHg; heart rate, 104 beats/min; and respiratory rate, 18 breaths/min. Pyridoxine was procured from another source and administered. Following therapy with pyridoxine she had no more seizures and had an uneventful recovery. She was extubated 9 hours after admission.

The tuberculosis epidemic is upon us and acute isoniazid (INH) intoxication has also increased at an alarming rate. During the years 1991-1995, a total of 11 INH related deaths were reported to the American Association of Poison Control Centers, compared to only two reported deaths during the preceding 8 years (1983-1990).

Pyridoxine (vitamin B_6) is the ONLY antidote for INH intoxication. Isoniazid inhibits the conversion of pyridoxine to its active form (pyridoxal phosphate), and also binds directly to pyridoxine causing inactivation. Isoniazid overdosage causes acute, severe pyridoxine deficiency. Pyridoxine is required to convert lactate to pyruvate, and to synthesize gamma aminobutyric acid (GABA), the main inhibitory neurotransmitter in the central nervous system (CNS). The predominant features of severe INH intoxication are thought to be related to GABA deficiency manifesting as CNS excitation: seizures, status epilepticus, coma and refractory anion gap metabolic acidosis.

Treatment involves decontamination and aggressive management of the seizures and acidosis with pyridoxine. A synergistic effect against seizures may be seen when diazepam is combined with pyridoxine, but diazepam alone is often ineffective. At least 15 grams of IV pyridoxine should be in your hospital pharmacy at all times! Pyridoxine is given in a gram for gram ratio with the ingested INH, requiring the use of LARGE amounts of pyridoxine for each patient. For example, a patient who takes a 7 gram overdose of INH will require treatment with 7 grams of pyridoxine IV. Initially, up to 5 gm of pyridoxine is given over 30-60 min. If necessary, the remainder of the dose is given in 500-1000 ml D_5W over 1-2 hours. If the amount of INH ingested is unknown, administer 5 grams of IV pyridoxine and repeat as needed until seizures are controlled.

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Charting A New Course

Resolutions Adopted By MPhA's House of Delegates

Crystal King, P.D., Chairman, House Resolutions Committee

While the Annual Convention means many things to many people, a chance to acquire much-needed CE, a chance to socialize with pharmacists friends old and new, and a chance to eat as many crabs as you can (without having to steam them yourself!), there is another thing that the Annual Convention means. The Annual Convention means it is time for the MPhA House of Delegates to convene to consider resolutions submitted by its members.

A member who submits a resolution does so because the member believes the topic of the resolution to be one which is important to the practice of pharmacy. This year, eleven such resolutions were submitted and considered by the House at the Second General Business Session on June 18, 1996. Nine of these were submitted prior to the Convention, and were reviewed by the MPhA Resolutions Committee. Two resolutions were submitted by members during the Convention, according to the bylaws. The following nine resolutions were adopted by the House, and are now MPhA policies which will be used to shape the future of the Association.

Sale of Tobacco in Pharmacies

Whereas, the sale of drugs that cause harm violates the standards of the American Pharmaceutical Association; and,

Whereas, the American Pharmaceutical Association has specifically adopted a position against the sale of tobacco products by pharmacists; and

Whereas, tobacco use is a preventable cause of death and disease; and,

Whereas, tobacco sales and promotions in pharmacies is counter-productive to sales of medications used to treat tobacco-caused diseases and to aid in smoking cessation;

Therefore, be it resolved that the Maryland Pharmacists Association opposes the sale of tobacco products in pharmacies.

Revision of Maryland Pharmacy Practice Act

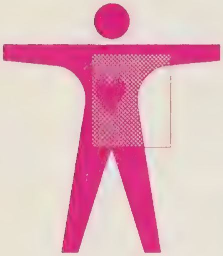
Whereas, the art and scope of pharmacy has experienced drastic change over the past several years; and,

Whereas, the Maryland Board of Pharmacy has developed changes and recommendations addressing these issues in the Pharmacy Practice Act; and,

Whereas, the Maryland Pharmacists Association Board of Trustees has adopted goals pertaining to the attainment of collaborative practice of pharmacists and the furthering of pharmacist-provided health services;

Therefore, be it resolved that the Maryland Pharmacists Association supports the Maryland Board of Pharmacy mission to revise the State Pharmacy Practice Act; and,

Be it further resolved that the Maryland Pharmacists Association pursue legislative efforts to further the passage of these revisions.



Denial of Patient's Right to Choose a Pharmacy

Whereas, the advent of managed care and mail order pharmacy has resulted in closed pharmacy networks; and,

Whereas, patients are frequently subjected to severe monetary penalties for utilizing an out-of-network or community pharmacy; and,

Whereas, the Maryland Pharmacists Association believes that patient needs are best met by regular, personal contact with a community pharmacist of the patient's choice;

Therefore, be it resolved that the Maryland Pharmacists Association pursue action to insure patient freedom of choice without any monetary penalty.

Utilization of Benefit Managers by Third Parties

Whereas, several programs are in progress which will allow a prescription from an authorized prescriber to be transmitted to a third-party benefit manager prior to transmission to the dispensing pharmacy; and,

Whereas, this process would allow for alterations to the original prescription by the third-party benefit manager; and,

Whereas, any alterations may or may not be so identified to the pharmacy;

Therefore, be it resolved that the Maryland Pharmacists Association supports and seeks legislation which would prohibit the insertion of third party benefit managers into the process of transmitting prescriptions between prescribers and pharmacies.

Pharmacists as Primary Care Providers

Whereas, with the evolving health care team concept and the importance of pharmacist care services; and,

Whereas, the pharmacist is an easily accessible, cost effective member of the health care team; and,

Whereas, this is a new role for pharmacists, for some members of the health care community and the public;

Therefore, be it resolved that the Maryland Pharmacists Association pursue means of educating the public and health care community of the value and the appropriateness of the role of the pharmacist as a primary care provider of the patient's health care team.

Changes in Requirements of Maryland Medicaid Prescriptions

Whereas, the requirement of the State of Maryland Medicaid Program requiring a written original prescription places undue hardship upon both the pharmacist and the Medicaid recipient; and,

Whereas, the Board of Pharmacy has accepted FAX prescription orders as a legitimate means of communication between pharmacists and prescribers;

Therefore, be it resolved that the Maryland Pharmacists Association shall pursue negotiations with the Maryland Medicaid program to allow pharmacists to accept prescription orders in accordance with established Board of Pharmacy laws and regulations.

Affiliation with the American Society of Health-System Pharmacists

Whereas, the Maryland Pharmacists Association represents all pharmacist members in the State; and,

Whereas, membership is not divided based upon practice setting; and,

Whereas, MPHA has affiliated status with the American Pharmaceutical Association, the NARD, and the American Society of Consultant Pharmacists;

Therefore, be it resolved that the Maryland Pharmacists Association pursue affiliated organization status with the American Society of Health-System Pharmacists.

Rohypnol

Whereas, Rohypnol, when used inappropriately, has been shown to be a clear and present danger to the public health; and, *Whereas,* the Maryland Board of Pharmacy would like to prohibit the inappropriate diversion of Rohypnol for use in date rape; and,

Whereas, the National Association of Boards of Pharmacy endorses Schedule I classification of Rohypnol;

Therefore, be it resolved that the Maryland Pharmacists Association support and encourage the development and promulgation of regulations by the Federal Drug Enforcement Agency and the Maryland Division of Drug Control to classify Rohypnol as Schedule I in Maryland.

Media Campaign

Whereas, pharmacists play an important role as health care educators, as health care providers, as consultants with expertise in recognizing adverse drug combinations and toxic medication levels; and,

Whereas, pharmacists are continuing to expand their role as integral and cost effective members of the health care delivery team; and,

Whereas, the Maryland Poison Information Center is building on a successful education and public service program that will promote the role of pharmacists; and,

Whereas, all pharmacists will benefit from an information campaign that emphasizes the essential and positive role of the pharmacist in patient health care;

Therefore, be it resolved that the Maryland Pharmacists Association accept the invitation of the Board of Pharmacy to plan, develop, and implement a health education and public service program with the Maryland Poison Information Center promoting the essential role of pharmacists as primary health care providers. **MP**

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FOR YOUR INFORMATION FROM THE BOARD

Dorothy Levi, R.Ph.

Secretary and Commissioner of the Maryland Board of Pharmacy

For pharmacy permit holders:

You must submit an application for a new pharmacy permit before December 1st of any year if you change the pharmacy's name, change the pharmacy's location and/or change the pharmacy's ownership (ex. individual to partner, individual to corporation, corporation to another corporation).

The $150 application fee is due for all changes except a change in location if the pharmacy's name and ownership stay the same.

For pharmacy permit holders that are selling or closing their pharmacy:

You must notify the Board of Pharmacy in writing at least 14 days in advance of the day that the pharmacy will be sold or closed. Then not later than 10 days after the pharmacy is sold or closed, notify the Board in writing.

You must notify the Division of Drug Control at least 7 days in advance of the sale or closing of the pharmacy and arrange for a closing inspection by the Division of Drug Control.

Information to be included in the notification of sale or closing:

1. Exact date of sale or closing
2. Copy of inventory required by DEA
3. Return pharmacy permit and State Department of Health and Mental Hygiene controlled dangerous substance registration for cancellation.
4. Names, addresses, telephone numbers and business entities to whom any prescription drugs in stock or prescription files were returned or transferred. If pharmacy is closing and not being sold, the permit holder, if a licensedpharmacist, or a designated licensed pharmacist shall retain possession of the pharmacy's documents considered to be medical records for the time period required by law.
5. If prescription drugs are disposed of at the sale or closing of the pharmacy, they must be disposed of by returning items to the distributor or manufacturer, transferring them to another pharmacy or destroying them in the presence of a representative designated by the Board.
6. If drugs are destroyed, the permit holder shall provide the Board with a certificate stating the date, time, place and manner of destruction; names, addresses and telephone numbers of persons responsible for destroying the drugs; and the name, dosage unit and quantity of each type of drug destroyed. Destruction of controlled dangerous substances require additional procedures, as required by the Federal Drug Enforcement Agency and the Division of Drug Control.

If you have questions, call the Board at (410) 764 - 4755.

Greetings, MPhA

Hello! Allow me to introduce myself. I am Connie Wagner, and am the new Administrative Assistant with the Maryland Pharmacists Association. I started with MPhA on July 1, and thus far have barely had time to breathe during my hours on the job.

I bring to the Administrative Assistant position experience working with independent pharmacies, wholesaler/vendor advertising campaigns, meeting planning and promoting membership for a buying group. Prior to coming to MPhA, I was with EPIC Pharmacies (MPPI), and served as the Marketing and Advertising Liaison for over 250 pharmacies in the Mid-Atlantic region for over three years.

I attended the Broadcasting Institute of Maryland and received a certificate in television production as a camera/editor. I attended Hagerstown Junior College and am anticipating returning to college this fall as a part-time student at Carroll Community College to major in psychology and marketing.

I reside with my son, Conley, in Hampstead, in Carroll County. I enjoy collecting antiques/junk furniture, art by the Wyeth family and baking homemade desserts.

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Continuing Education
Patient Counseling on New Drugs: Tramadol

J. Richard Wuest, R.Ph., Pharm.D.
Professor of Pharmacy Practice
University of Cincinnati
Cincinnati, Ohio

and

Thomas A. Gossel, R.Ph., Ph.D., Dean
Professor of Pharmacology and Toxicology
Ohio Northern University
Ada, Ohio

Goals

The goals of this lesson are to identify and discuss new drugs introduced to the marketplace during 1995-96, with special emphasis given to the new centrally-acting analgesic tramadol, comparing it to available narcotic and nonsteroidal analgesics.

Objectives

At the conclusion of this lesson, successful participants should be able to:

1. exhibit knowledge of the pharmacological classification and therapeutic considerations for tramadol and currently available analgesics;
2. select from a list, the indications, mechanisms of action, benefits, and limitations of tramadol and narcotic analgesics;
3. identify adverse effects, major toxicities, and drug interactions associated with tramadol as compared to previously available analgesics; and;
4. demonstrate an ability to counsel patients on tramadol.

A professional development program made possible by an educational grant from

SEARLE

Function and Mechanism of Pain Perception

Pain is one of the most common and important symptoms, and yet, it is one of the most difficult to treat. Pain has been described as the outcome of activation of electrical activity in afferent neurons by a number of stimuli including mechanical, thermal and chemical agents.

These neurons have sensory endings in peripheral tissues. They are different from other mechanical (touch) and thermal (heat/cold) receptors in that they have a higher threshold for firing and sending impulses to the brain. They are activated by stimulation sufficient to cause some degree of tissue damage. The high threshold of pain receptors leads to the ability to override minor pain by rubbing the area (mechanical stimulation) or applying cold or heat (thermal stimulation).

Once pain impulses leave the periphery, they enter the central nervous system. It appears that there are two major pathways for pain within the CNS: the afferent (incoming) pathway and the efferent (descending) pathway.

The afferent pathway is objective in that it tells us we are experiencing pain, as well as the intensity and the location

Table 1
New Centrally Acting Analgesic

Generic	**Trade Name**	**Availability**	**Dosage Regimen**
Tramadol	Ultram	50mg tablet	50-100mg q 4-6 h

(however, pain is sometimes referred to another area of the body as in angina pectoris). The efferent pathway is subjective in that it determines our emotional response to pain.

These two pathways determine how we perceive pain and how we will react to it. It is believed that the non-opioid analgesics act mainly on the afferent pathway and the opioids act to the greatest extent on the efferent pathway.

Many endogenous chemicals are involved in the sensation we perceive as pain. Among them are bradykinin, cholecystokinin, dynorphin, endorphins, enkephalins, glutamate, interleukins, leukotrienes, norepinephrine, prostaglandins, serotonin, somatostatin, substance P, vasoactive intestinal polypeptide, and possibly hundreds of other proposed but not yet discovered substances. Pain has been classified a number of ways including by its components: discriminating and alerting.

The discriminating or localized component helps the person determine the nature, intensity, and location of pain. This type of pain is useful in diagnosing the underlying condition causing it. The alerting or affective component interrupts the person's activity and changes his or her behavior because it demands attention.

This component is also a great learning tool since most of us will avoid activity that has previously caused pain. This latter component is critical to our intuitive survival mechanisms. However, when pain becomes chronic, unremitting and unalleviated, serious pathopsychologic changes can occur.

Pain has been categorized into three additional groups: acute pain in which the cause can be identified (i.e., broken/fractured bones, lacerations, trauma); chronic pain of known cause (i.e., cancer pain); and chronic pain of unknown cause.

Still another classification of pain is somatic and visceral. Somatic pain describes an intense, sharp and localized sensation such as a response from an insect sting. It is sometimes referred to as a "stinging sensation." Visceral pain is characterized as dull, aching, and diffuse. It is sometimes referred to as a "burning sensation."

Opioid Receptor Function

Opioids act by reacting chemically with specific receptor sites on CNS cells. There are currently three known subgroups of receptors and 18 endogenous peptides with opioid-like activity. More will certainly be uncovered in the future. The endogenously produced peptides that are components of pain are thought to act in the efferent pathways, i.e., our response to the sensation of pain. Of the 18 peptides discovered so far, the two most important groups are -called endorphins and enkephalins. Opioid analgesics mimic their activity.

The three definitively expressed opioid receptors have been labeled delta, kappa, and mu. A fourth possible, but not yet universally accepted, opioid receptor has been labeled sigma. Of these receptors, the mu subgroup seems to be the most important for the action of opioids and tramadol.

Besides analgesia, the mu receptors also mediate euphoria, miosis and respiratory depression. The kappa receptors, while they do appear to be capable of producing analgesia at the spinal level, are not considered to be of prime importance for the action of analgesics. Instead, they mediate sedation and miosis.

Delta receptors have a very high affinity for endogenous enkephalins, but not exogenously administered opioids. While densely present in the limbic system, the dorsal horn of the spinal cord and several areas in the brain, the association of delta receptors with analgesic activity has not yet been determined. Delta receptors do mediate hypotension, miosis, dysphoria and hallucinations.

The function of sigma receptors is still unknown. They may be the primary receptor for endogenous enkephalins, but they also appear to react with other chemicals besides opioid analgesics. At one time it was believed that these receptors accounted for anxiety, hallucinations and bad dreams associated with some opioids.

This leaves us with the current theory that mu receptors are the primary subgroup of opioid receptors. Opioid analgesics and tramadol have affinity for and intrinsic activity with mu receptors, and these receptor are considered to be the point of activity for pain relief with these drugs.

Mechanism of Action of Opioids

The term opioid refers to any substance that produces morphine-like effects that can be blocked by narcotic antagonists such as naloxone. Morphine is derived from opium, hence the name opioid. Today, however, there are a number of synthetic narcotic analgesics such as meperidine and methadone that are also classified as opioids.

The term opioid has also been assigned to the receptors that morphine and morphine-like drugs attach to in the body, as described above. This is because these receptors were discovered before endorphins, enkephalins and similar peptides.

Opioids attach to and stimulate opioid receptors thereby altering the individual's perception of pain. They are considered to be the agents of choice for moderate to severe pain. Their major drawbacks are sedation, constipation, tolerance, and possibly addiction.

Nonsteroidal Anti-inflammatory Drugs (NSAIDs) Mechanism

A number of chemicals are involved in stimulating pain nerve impulses and transmitting them to the brain. Among these are bradykinin and related peptides which cause the release of several prostaglandins which, in turn, greatly enhance their direct action on nerve endings.

Prostaglandins themselves do not cause pain. They enhance the pain-producing effects of other chemicals such as bradykinin, serotonin, and histamine. Histamine, however, is more involved in inflammation and itching than pain.

The major analgesic action of NSAIDs (as well as acetaminophen and aspirin) is inhibition of cyclooxygenase, an enzyme involved in prostaglandin synthesis. Therefore, they decrease sensitization of pain pathways.

Acetaminophen (APAP), aspirin (ASA) and NSAIDs are considered to be agents of choice for mild to moderate pain. While some patients believe they get better relief from one agent versus another, across the board they are equally effective. Side effects can be a concern with these analgesics. With ASA and NSAIDs, gastric upset and ulceration are major adverse effects in susceptible persons.

Another potential problem in the treatment of pain with these drugs is that APAP, ASA and most NSAIDs have an analgesic dosage ceiling, above which they provide no additional pain relief. For APAP and ASA, the ceiling is between 650 and 1300mg. Some NSAIDs have a higher analgesic ceiling. For example, ketorolac (Toradol) can equal the effects of oral narcotic in analgesic activity.

Combination Analgesic Products and Other Drugs Used to Treat Pain

Since they act by totally different mechanisms, it is rational to use combination products containing opioid and nonopioid analgesics. This can actually improve pain relief by maintaining the nonopiod component at or below its analgesic ceiling while reducing the need to escalate the opioid dosage.

These combinations are among the few examples (along with diuretic/antihypertensive combinations) of products that exhibit true synergistic action useful in therapeutics.

Other analgesic combinations approved by the FDA include meprobamate/ASA and chlorzoxazone/APAP for muscle spasms causing pain; butalbital/ASA or APAP for tension headache; antihistamines/ASA or APAP/mild diuretic for premenstrual pain; and antihistamines/ASA or APAP for sleeplessness associated with pain.

Although caffeine has been an ingredient in analgesic products for years, it has not yet been proven to be effective in pain relief.

Other drugs used to treat pain include tricyclic antidepressants (TCAs) and anticonvulsants. The TCAs (usually amitriptyline or imipramine) are effective in treating neuropathic pain (pain associated with problems in the neurons) which is resistant to opioids, diabetic neuropathy (nerve damage caused by the complications of diabetes) and postherpetic neuralgia (pain caused by herpes viruses residing in neurons, especially following flare-ups of shingles).

Anticonvulsants, in spite of the fact that they have no discernible analgesic effects, are effective in treating some chronic pain conditions. Carbamazepine is considered to be the agent of choice in treating trigeminal neuralgia (tic douloureux), i.e., severe pain along the bridge of the nose and upward into the crown of the head.

Tramadol

Tramadol (tram-A-doll), (Ultram) (UHL-tram) is the first of a new type of centrally acting analgesics. It is also the first analgesic that is not an NSAID to be introduced to the marketplace in over 10 years. It is approved for use in treating moderate to moderately-severe pain. Tramadol shares some chemical structural configurations with morphine.

Tramadol had been available in Europe since 1977 in tablet, capsule, oral drop, injection, and suppository dosage forms. Developed in Germany, it is currently the most widely prescribed analgesic there.

Mechanism of Action. In some ways, tramadol acts similarly to opioids. It has been shown to bind with mu, kappa, and delta receptors, but its analgesic activity is linked to it being a weak agonist to the mu subtype of opioid receptors. Like opioids, tramadol alters the person's perception of pain. It also enhances the action of norepinephrine and serotonin released in response to pain stimuli. Since these neurotransmitters are involved in the thought process, it is believed that this action also modifies how the person perceives the pain.

It has been stated that tramadol prevents pain impulses from traveling to the brain, and enhances the body's natural mechanism for modifying how the brain monitors pain.

It is known that tramadol does not inhibit the production of prostaglandins or affect bradykinin. This is used in marketing the drug by positioning it as an analgesic that does not cause gastrointestinal upset or ulceration, as do the NSAIDs.

It has also been determined that tramadol's affinity for mu receptors is 10 times less than that of codeine and 6000 times less than morphine. While the manufacturer is not permitted to promote tramadol as being nonaddicting, it is not classified as a drug with abuse potential and it is not covered under the Controlled Substance Act. Also, manufacturers may not promote it as having enhanced potency over other agents. Ortho McNeil will monitor its sales to watch for possible abuse.

Tramadol has been used in more than 39 million patients and there are only 152 reported cases of possible abuse. Most of these persons were abusing other drugs as well.

Drug Interactions. Since tramadol affects norepinephrine levels in the synaptic areas, it should not be given concurrently with monoamine oxidase inhibitors. The manufacturer contraindicates the use of Ultram in patients acutely intoxicated with alcohol, hypnotics, centrally acting analgesics, opioid or psychotropic drugs. The result could be increased CNS side effects.

It does not appear that tramadol would be involved in drug interactions based on displacement of other drugs from protein binding because it does not have significant affinity for protein binding sites.

The significance is not known at this time, but tramadol may be metabolized to some extent by the P-450IID6 isozyme of the cytochrome P-450 enzyme system. It does exhibit competitive inhibition by quinidine for this pathway, but more time and studies are needed to determine the significance of this.

Side Effects. Unlike opioids, tramadol has not produced significant respiratory depression, nor has tolerance been reported.

Adverse effects were reported for tramadol in clinical trials differently than most drugs since it is considered to be unethical to deprive a patient in pain from receiving analgesic merely to complete a drug study. Therefore, adverse effects are reported for tramadol compared to acetaminophen 325mg/codeine 30mg (APAP/COD) and aspirin 325mg/codeine 30mg (ASA/COD).

Those occurring above the five percent level during the first seven days of treatment with tramadol (mean daily dose = 250mg) were dizziness 26 percent, compared to 26 percent for APAP/COD and 16 percent for ASA/COD; nausea 24 percent versus 29 and 35 percent; constipation 24 percent versus 51 and 34 percent; headache 18 percent versus 17 and seven percent; somnolence 16 percent versus 24 and 19 percent; and vomiting nine percent versus five and six percent.

Two other studies with the mean dose of 150mg per day showed only nausea (six percent) and dizziness (five percent) at the five percent or higher level. This leads to the recommendation that patients be started on tramadol at 50mg three times a day. They can then be titrated upward until pain is relieved or the 400mg per day dosage regimen is reached to reduce the occurrence or magnitude of adverse effects.

Dosage. The usual adult dosage for tramadol is 50 to 100mg three to four times a day, at six to eight hour intervals. Most patients, including those with cancer, reportedly respond to these doses. The maximal daily dose of tramadol is 400mg.

While age is not a definitive criteria for dosing tramadol, some geriatric patients with renal or hepatic impairment may require lower doses. The recommended daily dose for these patients is 300mg, in divided doses as listed above.

For patients with compromised renal function, the recommended dosing is 50 to 100mg every 12 hours, and for patients with cirrhosis, 50mg every 12 hours.

Patient Counseling

As with any analgesic, patients should be advised to take their medication as directed by their doctor. Taking more than the prescribed dose can lead to toxicity and not taking enough can prevent attainment of the desired therapeutic effect. If pain is not relieved with the prescribed dosage, patients should inform their doctor so the dose can be adjusted or another agent selected.

Ultram tablets can be taken with or without food. Taking the dose with a glass of water or other fluid can enhance its onset of action and reduce potential gastric upset (which is rare and significantly less than that caused by NSAIDs).

As with any drug acting on the CNS, Ultram may cause dizziness or drowsiness and impair the patient's mental or physical abilities. This may affect his ability to drive or operate hazardous equipment.

Additional counseling information can be found in Table 2.

Table 2
Patient Counseling Tips for Ultram

* Ultram is used to relieve pain

* Ultram may be taken without regard to meals. If it upsets yur stomach, take it with food. It is best to either always take the dose on an empty stomach or with food.

* Some patients have experienced dizziness, blurred vision or drowsiness from this medication. If you do, be careful driving or performing hazardous tasks. Alcoholic beverages can increase the drowsiness effect.

* Some patients experience constipation after taking Ultram for a few days. Increasing the amount of bulk fiber in your diet (i.e., bran, psyllium or fresh fruits) and drinking lot of fluids can help prevent this.

* Do not take prescription drugs while taking this medication without checking with your doctor.

* There are few side effects reported with Ultram. However, inform your doctor if you experience dizziness, drowsiness or lightheadedness, nausea or vomiting, difficult breathing, excitement, unusual heartbeat, profuse sweating, skin rash, or any other bothersome or unusual side effect.

MPhA members can receive one contact hour of CE by completing and returning the CE quiz on page 17 of this issue. This program has been approved for one credit hour (0.1 CEU's) of ACPE approved continuing education. The Maryland Continuing Education Coordinating Council is an approved provider of continuing education programs for pharmacists by the American Council on Pharmaceutical Education. ACPE# 144-999-96-016-HO1

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Continuing Education Quiz - July/August 1996

Patient Counseling on New Drugs: Tramadol

This month's questions are taken from the article on Tramadol that appears in this issue. Circle your answers to the following questions and mail the entire page to *Maryland Pharmacist CE*, 650 West Lombard St., Baltimore, Maryland 21201 - 1572 or FAX it to (410) 727 - 2253. There is **no charge** for this quiz for MPhA members (non-members $5.00). The completed quiz for this issue must be received by August 31, 1997. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly. **ACPE # 144-999-96-016-H01**

Name____

Address____

City/State/ZIP____

1. Somatic pain describes all of the following sensations EXCEPT:
a. intense.
b. dull.
c. localized.
d. sharp.

2. All of the following are known to be opioid receptors EXCEPT:
a. alpha.
b. delta.
c. kappa.
d. mu.

3. Which of the following statements about tramadol is true?
a. It alters the perception of pain.
b. It is a controlled substance.
c. It causes significant gastric irritation.
d. It affects bradykinin production.

4. Which of the following sensory endings in peripheral tissues has the highest threshold for firing and sending impulses to the brain?
a. Cold
b. Touch
c. Pain
d. Heat

5. The major analgesic action of the nonsteroidal anti-inflammatory drugs is due to their inhibiting:
a. bradykinin.
b. cyclooxygenase.
c. histamine.
d. norepinephrine.

6. The afferent pathway for pain tells us all of the following concepts EXCEPT:
a. we are experiencing pain.
b. the intensity of the pain.
c. the location of the pain.
d. our emotional response to pain.

7. Tramadol acts by affecting all of the following components of pain EXCEPT:
a. norepinephrine.
b. mu receptors.
c. prostaglandins.
d. serotonin.

8. Which of the following is an appropriate dosage regimen for tramadol?
a. 10mg every 12 hours.
b. 30mg every 8 hours.
c. 50mg every 6 hours.
d. 300mg every 4 hours.

9. Tramadol acts on the primary subgroup of opioid receptors which are referred to as the:
a. alpha receptors.
b. beta receptors.
c. gamma receptors.
d. mu receptors.

10. The non-opioid analgesics reportedly act mainly on the:
a. afferent pain pathway.
b. efferent pain pathway.

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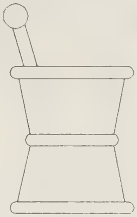

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MPhA PHARMACIST'S JOURNAL

Task Force:

The Future of Pharmacy Practice

The Possible Role of Antihypertensive Medication in Sexual Dysfunction

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War Time Pharmacists:

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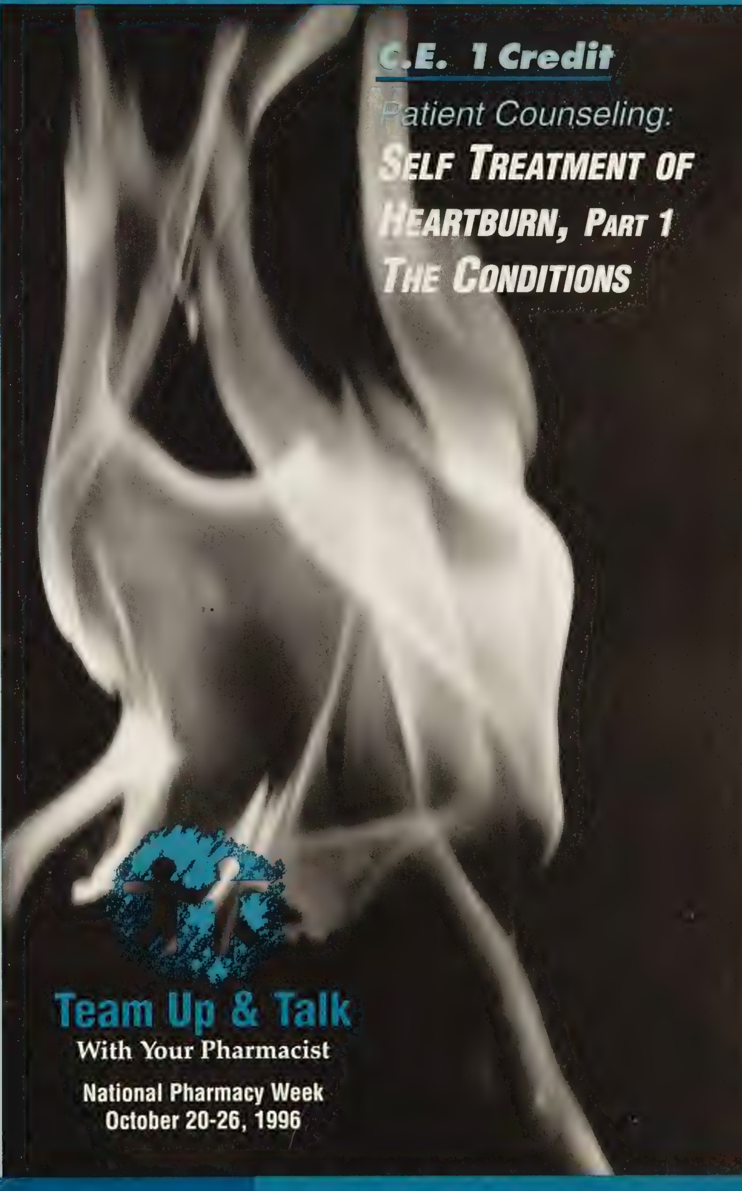
Patient Appreciation... Etiquette



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SELF TREATMENT OF HEARTBURN, PART 1 THE CONDITIONS

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Our *purpose* is to promote the common interest of those engaged in or associated with the practice of Pharmacy in the State of Maryland.

To Promote and safeguard the public health and welfare of the people of the State of Maryland.

To cooperate with other health care professionals and organizations.

To promote the proper use of drugs, medicines and health care devices.

To promote the professional, financial and economic interest of its members.

Pharmacists Journal

The Official Publication of the Maryland Pharmacists Association

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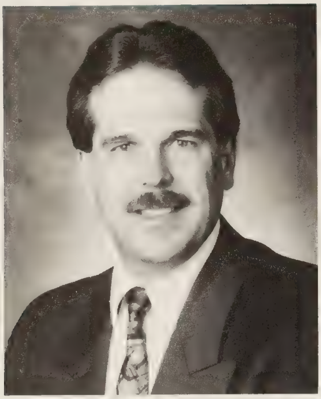
President's Commentary

Patient Appreciation (Etiquette)

Ernest Testerman, P.D., President



It's Friday afternoon and the prescription counter is laden with prescriptions to fill. My feet hurt, my ears hurt, my head is about to explode and most important of all, my bladder is full. The District Manager has just left after having explained to me the virtue of "Customer Service" per company policy. It seems that during one of our busier times a customer needed to know where to find the Tylenol, which I gave most willingly. The customer however did not like the tone I used in telling her where the analgesic section was in the store. OK, back to work.

Now it's back to filling those prescriptions that have been waiting for my professional scrutiny. This one seems to be straight forward, just wrap, slap and stack. WARNING, DUR MESSAGE. I knew it was too good to be true. There is no such thing as an easy prescription to fill any more. It seems the patient is on Seldane from the allergist and the family doctor wants him on Erythromycin. OK, I will call the doctor and have the prescription switched to another antibiotic. You have reached the office of Dr. X, if this is a medical emergency hang up immediately and dial 911 or go directly to the emergency room. If you need a refill on your medication please press 1 now. It's my lucky day, I will have to deal with the automated receptionist before getting through. So, all of a sudden a quick prescription becomes a 15 minute adventure. Now we have a new antibiotic for the patient and we are on our way. RX REJECTED PATIENT NO LONGER COVERED. OH GREAT, another problem for my pharmaceutical knowledge to resolve, to ask the patient if he has a new card or if he wants to pay cash. PAY CASH? ARE YOU CRAZY? MY CARD IS GOOD. YOU JUST CALL MY INSURANCE COMPANY AND FIND OUT WHY I'M NOT COVERED ANYMORE. Ah, again we get to play automated telephone tag for this information. Yes, you are covered under the plan, they accidentally removed you from their records so give me a minute and your prescription will be ready. Oh, whatever happened to the days of lick, stick and pour? The prescription that should have taken about three minutes to fill has now taken 15 to 20 minutes; what productivity. Now a few of the other patients begin to return to pick up their prescriptions that are not done. "Where's my prescription? I dropped it off 20 minutes ago. What's taking so long? Its only for Percocet." Now everyone begins to complain, tempers flare, the pressure mounts and my bladder is still full. Where is all my help when I need it? I need to go over to the consultation area to tell these complainers where they can stuff it. However, I will not erupt because I'm a professional and know the patient needs my understanding. Don't they know I'm working as fast as I can while doing the best I can with the least amount of help possible to fulfill their pharmaceutical needs. Does this scenario sound familiar? Do we need a solution?

Yes, we do need a solution and I have an idea "Patient Education." Lets develop a Patient Education program entitled "Patient Appreciation" (politically correct title for Proper Patient Etiquette) to be distributed via pamphlet or played on video in the waiting areas of the pharmacy for viewing by the patient as they wait for their prescription(s). Maybe its time for pharmacy to develop educational programs that inform the patient of these non-compensated, non-pharmaceutical services which pharmacists continuously provide on a daily basis in addition to pharmaceutical services. The patient needs to be educated that these services are above and beyond normal pharmacy practice. If the patient expects their pharmacist to be an insurance agent, personal secretary, extended family or counselor, they should be willing to pay compensation for these additional non-pharmaceutical services. If we charged for these types of services, additional help could be employed which could free up pharmacists to serve the patient better. Since the pharmacist work load would be reduced, a more relaxed atmosphere would exist and the pharmacist could communicate more effectively with the patient. This would then lead to one of our ultimate goals "Great Pharmaceutical Care."

The Maryland Pharmacists Asociation would like to thank those who contributed towards the purchase of new computer equipment for the MPhA office

The Baltimore Metropolitan Pharmacists Association, Montgomery/Prince Georges' Pharmacists Association, Upper-Bay Pharmaceutical Association, Giant Foods, James Tristanti, P.D., Harford & Belair Pharmacies, Arnold Davidov, P.D., Tuxedo Pharmacies, and SAMPA

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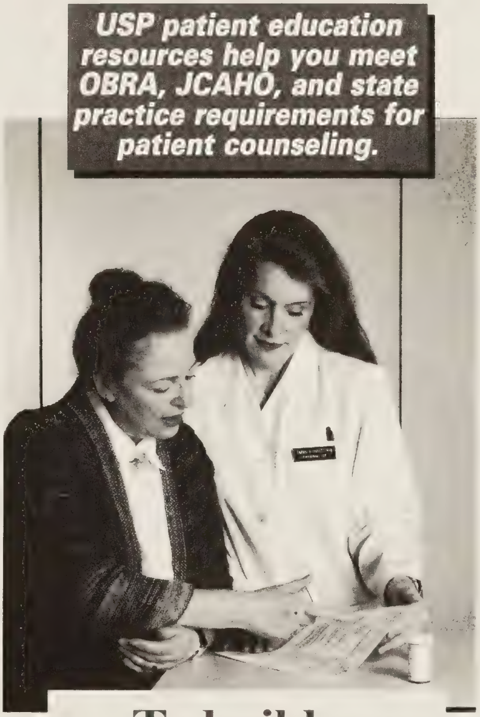

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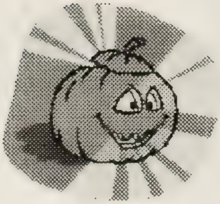

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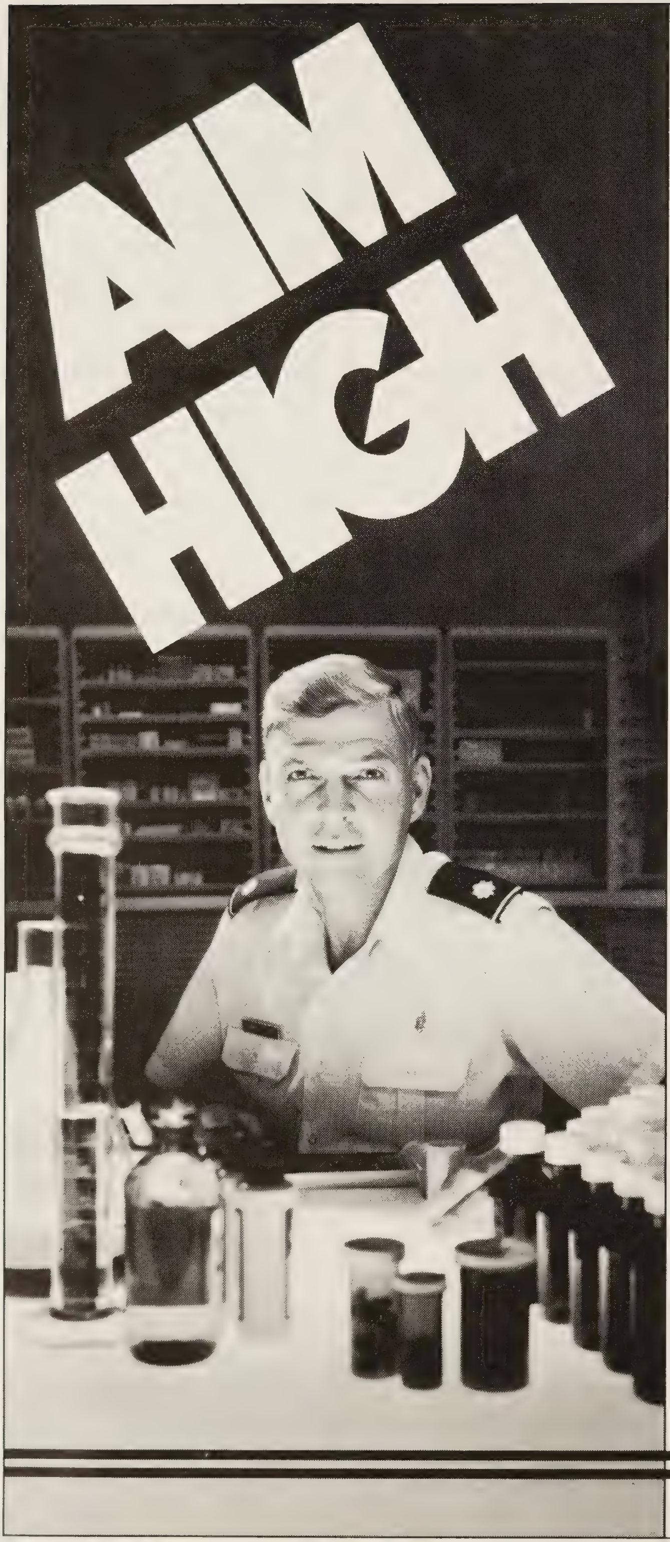

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SECOND YEAR STUDENT.
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Knowledge is expanding about the factors that influence sexual function. Sexual function (interest, erectile function, and orgasmic ability) requires a complex interaction of endocrine, psychological, neurologic, and vascular systems. A current study has demonstrated that sperm concentration and semen volume have decreased, which suggests that the male population may have been exposed to a harmful environmental factor. An increase in the number of sexual partners for males has proportionally increased the likelihood of urinary tract infections and infertility. In addition, a great number of drugs have been found to act as a toxic substances, affecting both male sexual response and fertility. (Prisant 1994) Drugs of abuse, as well as various prescription drugs, can create an obstacle in "normal" sexual function. This paper will explore the role of antihypertensive medication, specifically thiazide diuretic, on sexual dysfunction giving evidence to impact on quality of life and compliance.

Medications may have a adverse effect on male libido, erection, ejaculation and orgasm, as well as on fertility. Libido may be decreased by drugs that block dopamine or testosterone, or that cause dysphoria. Erection may be decreased by drugs that divert blood flow from the penis, or medications that affect spinal reflexes. Ganglion blockers may also inhibit erection. Alpha adrenergic agents block enervation of the vas deferens and epididymis, causing decreased emission and therefore less stimulus for ejaculation. Anorgasism is caused by medications that inhibit ejaculation. Retrograde ejaculation may occur due to alpha sympathetic blockage of the internal sphincter. The group of medications that are most likely to cause an adverse reaction of sexual dysfunction are: CNS depressants, antihypertensive agents, anticholinergics, psychotherapeutic, hormones, and anti-neoplastic agents, in addition to other agents. (Wilson, 1991)

Medically-induced sexual dysfunction impacts both quality of life and medication compliance. Medications, especially those that are vasoactive, are likely to interact with the complex endocrine, psychological, neurologic, and vascular systems necessary for normal sexual function. Cardiovascular medications are the most frequent offenders, but virtually any medication with anticholinergic or sympatholytic effects can impair sexual function.

Sexual dysfunction, particularly erectile dysfunction, has been reported with the use of anti- hypertensive medication. Antihypertensive drugs have been associated with sexual dysfunction among treated hypertensive patients, although many of the associations are based on case reports. Nevertheless, hypertensive vascular disease, aging, diabetes, physical symptoms, emotional disturbances, and personal perceptions are very significant confounding variables that make the assessment of sexual dysfunction greatly troublesome. (Prisant 1994)

Although sexual dysfunction is associated with antihypertensive therapy, it is possible that there may be pathophysiologic reasons related to lowering the blood pressure or the consequence of hypertensive vascular disease process. The relationship of hypertension and antihypertensive medications to sexual dysfunction remains unclear.

Diuretic therapy is generally perceived to be well tolerated with relatively few side effects, and most often used as a single therapy medication in the treatment of mild hypertension or included in combination therapy. Given the high prevalence of asymptotic mild hypertension, evidence of substantial impact on quality of life by diuretics could affect a large segment of the population.

Chang et al demonstrated in a randomized placebo-controlled trial of the effect thiazide diuretics on the quality of life in mildly hypertensive men between the ages of 35 and 70 years. After a one month washout period off diuretic therapy, the men were randomized to a two month trial of a thiazide diuretic treatment or placebo. At the end of the trial, 176 men completed a confidential self-administered questionnaire assessing aspects of social performance, general well being, and emotional and physiologic states. Patients taking diuretics reported significantly greater sexual dysfunction than control subjects, including decreased libido, difficulty in gaining and maintaining an erection, and difficulty with ejaculation. However, there were no differences between placebo and diuretic in measures of mood, general social/ recreational activities. This study has elucidated the area of thiazide induced sexual dysfunction, additional study is needed to further evaluate this association. Self-reported sexual dysfunction may underestimate or overestimate sexual function. The sexual adverse reactions of thiazide diuretics may also dissipate with longer treatment. In contrast, studies have provided evidence of long-term sexual dysfunction related to thiazide diuretic therapy. (Chang 1991)

Sexual dysfunction associated with thiazide diuretic therapy has also been reported in several other studies. The Medical Research Council Trial reported a 17% withdrawal rate from thiazide therapy for men, with impotence as the cited reason in 20% of men who withdrew from the study. However, this randomized placebo-controlled single-blind trial added methyldopa as an additional treatment for hypertension in a non-randomized fashion, and rates of dual therapy are not reported. (The Medical Research Council Trial, 1985)

The Hypertension Detection and Follow-Up Study reported that 5% of male patients discontinued chlorthalidone therapy due to sexual problems. Hogan et al compared self-reported sexual dysfunction symptoms between men receiving antihypertensive therapy and normotensive control subjects, and found significantly greater sexual dysfunction among those taking diuretic therapy. While these studies suggest a casual relationship between thiazide diuretics and sexual dysfunction, there is evidence that some hypertensive patients report sexual dysfunction in the absence of thiazide therapy. What is not established is the specific effect of diuretic therapy when compared with a blinded placebo control. (The Hypertension Detection and Follow-Up Study, 1979)

Clinical trials have increased focus on the quality of life and are reflective of the broader view of health status, one that encompasses aspects of physical, mental, and social well-being. Although studies have described the effects of antihypertensive therapy on qualify of life indexes, none have adequately focused on thiazide therapy. The absence of quality of life effects may be viewed in the light of the inability to detect small effects. The larger or more prolonged study of Croog et al did report other adverse quality of life effects from diuretic use in association with other antihypertensive agents. In particulars, patients requiring additional diuretic therapy reported additional distress. (Croog, 1986)

Physicians should be prepared to facilitate awareness and understanding of sexual dysfunction. Generally, sexual dysfunction increases with age and may be associated with physical and emotional symptoms. Most often sexual dysfunction is associated with impairment of qualify of life and non-compliance of medication. Individual variances must be considered in the evaluation of pharmacological effects on sexual function. Most often, sexual dysfunction may be unreported unless the physician specifically probes this issue. However, most patients may be willing to respond to questions of a personal sexual nature, if they are aware of the relevance for comprehensive medical treatment. Physicians should select medications that are least likely to have effects on sexual response, especially if there is sexual dysfunction history. It is vital that physicians feel comfortable discussing sexuality with their patients, or direct them to someone who does feel comfortable.

The medical literature regarding the role of thiazide diuretics in sexual dysfunction is characterized by an exclusive reliance on questionnaires-aquantitative method from social science applied to a problem in medicine. Studies utilizing questionnaires may not provide objective information on sexual dysfunction; however, the response rate to direct questioning may be less than the response rate on a questionnaire and may be affected by the gender or race of the interviewer. Physicians should be aware that patients may under report sexual dysfunction symptoms even when directly questioned.

Sexual dysfunction in female and African-American hypertensive patients is poorly documented. A case should be made to explore these areas further. In addition, since group data may have the propensity to hide individual pharmacological effects, it may be helpful to obtain baseline sexual function data on patients prior to initiating therapy with an anti-hypertensive medication.

A cardiologist and a family practice physician were recently queried on the impact of diuretic therapy- induced sexual dysfunction in their hypertensive patients. I was astonished to discover that although both physicians were aware of the unfavorable side effect of sexual dysfunction associated with diuretic therapy, neither physician bothered to counsel their patients before initiating thiazide diuretic therapy for their hypertensive patients. Furthermore, both physicians preferred to wait until the patient experienced the adverse reaction of sexual dysfunction before consultation.

Although both physicians whom I queried were familiar with the Medical Research Council's findings that the use of Beta-Blockers (propranolol) was associated with the withdrawal from treatment due to sexual impotence, only the cardiologist was aware of the fact that the withdrawal for the Beta-Blocker group was actually at a lower frequency than for the group receiving thiazide therapy. (Medical Research Council Working Party, 1985) It is interesting to note that with my research, I found that the primary care physician pledges to counsel antihypertensive patients on sexual dysfunction prior to treatment with thiazide diuretic therapy. Both physicians preferred to prescribe a thiazide combination agent for their newly diagnosed hypertensive patients. The thiazide combination agent is preferred by both physicians due to its reported safety record and patients compliance and patient satisfaction.

This topic is by no means complete. The research yet to be done is boundless regarding the potential for sexual dysfunction during treatment with a thiazide diuretic agent. Thiazide diuretics are the most commonly prescribed antihypertensive agents in the treatment of hypertension in the United States, the effect on sexual function should be an important consideration in therapeutic decision. (Prisant, 1994) The impact of sexual dysfunction, especially in hypertensive patients treated with thiazide diuretics, on patient compliance is considerable.

A quote from the cardiologist:

> "As the physician and future physician transverse down the minefield of the kinds of antihypertensive agents there are out there. Certainly one must place the sexual dysfunction side effect at the top of his list of powerful and limiting side effects in antihypertensive therapy that he prescribes for his patients."

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Acknowledgment to the physicians that I consulted for this research paper.

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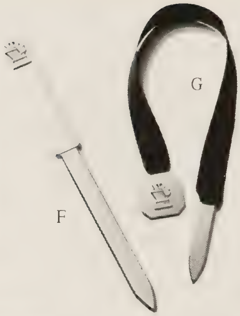

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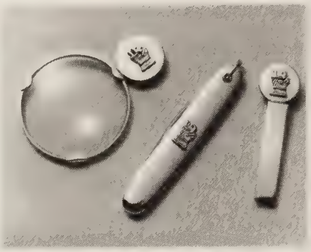
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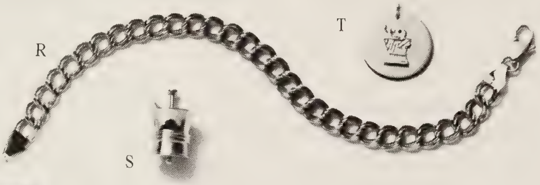

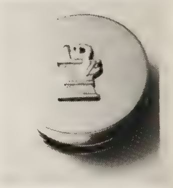
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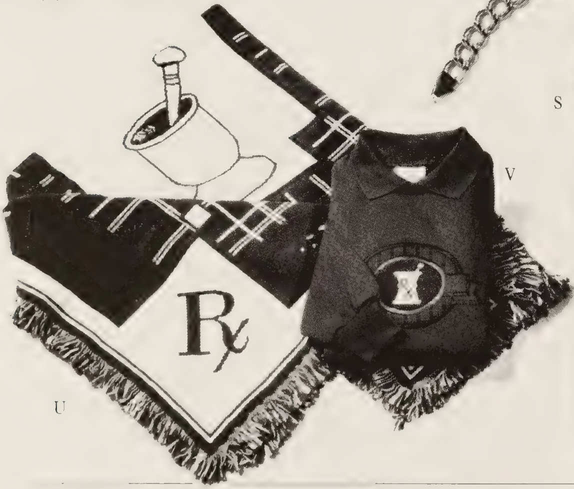

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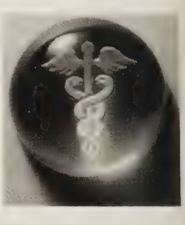
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Executive Summary
Maryland State Board of Pharmacy
Task Force on the Future of Pharmacy Practice

Dorothy Levi, R.Ph., Secretary

What is the Role of the Maryland State Board of Pharmacy?

The role of the Board of Pharmacy is to assure that the practice of pharmacy is appropriately defined in statute and regulation, to protect the public health by the testing of professionals, and licensing qualified pharmacists and pharmacy businesses, and to investigate pharmacy conditions/ situations that pose a danger to the public health. Moreover, its role is to continuously assess and redefine the Board and its functions in the advancing world of interdisciplinary health care and to direct, monitor, and discipline those who threaten the safety of the public health.

Why Review and Revise the Pharmacy Practice Act?

There have been many changes and advances in the practice of pharmacy since Title 12 of the Annotated Code of Maryland was written in 1902. The health care environment has changed dramatically since the last revision in 1969 with the advent pharmaceutical care and advances in the delivery of health services. The Board decided to take a comprehensive look at its laws and associated regulations to insure that pharmacists and pharmacies were prepared to transition the efficient, cost effective and appropriate practice of pharmacy into the twenty first century. The report of the PEW Health Professions Commission advocated an interdisciplinary approach to patient care, noting the emerging role of the pharmacist in providing drug therapy by a collaborative process of selecting appropriate drug therapies, educating patients, monitoring patients, and continually assessing outcomes of therapy. The revised practice act will enable both the pharmacist to participate in this interdisciplinary approach to patient care, and the Board to react to changes in health care to protect the public health.

What is the Role of Pharmaceutical Care in the Changing Health Care Environment?

The practice of pharmacy is consistent with the concept of managed care. It encourages the interaction of allied health professionals and the utilization of the most advanced technology and products to promote improved health outcomes for the lowest cost. Defining pharmaceutical care in the Maryland Pharmacy Practice Act opens new pathways for competent health professionals to provide services under scopes of practice that are interrelated and which will lead to improved access to primary health services at reduced costs.

What has the Task Force on the Future of Pharmacy Practice Accomplished?

Despite request from some segments of the business community in Maryland for a diminished role for statutes and regulations, pharmacists representing all aspects of pharmacy industry recommended and endorsed additions and modifications to the existing statutes and regulations designed to preserve the safe practice of pharmacy in the state. The Board and the Task Force have defined and redefined those key aspects of pharmacy practice that are undergoing rapid change. The Task Force undertook a thorough review of the existing Maryland Pharmacy Practice Act, considering national models of the ideal pharmacy practice act and changes recently promulgated in other state pharmacy practice acts, in order to make recommendations concerning the promulgated in other state pharmacy practice acts, in order to make recommendations concerning the necessary additions and changes needed to remain current with state of the act pharmacy practice. The Task Force made recommendations in six areas: professional judgement, pharmacist workload, the pharmacist's responsibilities for patient receiving controlled substances, non resident pharmacy, assistance in the medication distribution process, and scope of practice. A summary of the Board and Task Force recommendations follows.

Recommendations on Professional Conduct

The Board plans to develop a new chapter of regulations defining unprofessional conduct to accomplish the following: (1) outline activities which are unprofessional and for which a pharmacist may be charged with unprofessional conduct, (2) give a pharmacist a legal ground for denying service to patients presenting prescriptions which cannot be verified with the prescriber, and (3) include a listing of pharmacist responsibilities when dispensing controlled dangerous substances to a patient.

Recommendations for issues falling under the category of unprofessional conduct as discussed by the Task Force are as follows: demonstration of a willful or careless disregard for the health, safety, or welfare of a patient; involvement in illegal drug trafficking when the pharmacist either knew or should have known of the licensed health professional's involvement; fraudulent compensation for services or products; engaging in conduct which substantially departs from the standards of care ordinarily exercised by a pharmacist; failure to verify a prescription when there is a doubt as to the appropriateness, validity, or legitimate medical purpose of the prescription; and inappropriate therapeutic substitution.

Recommendation In Pharmacist Workload

A provision is recommended to be added to the Pharmacy Practice Act that requires pharmacy permit holders to maintain adequate pharmacy personnel, automation, and other technology to give the pharmacist employee sufficient time to utilize his or her professional knowledge and training to competently perform the functions of a pharmacist as defined in law and associated regulations.

The Task Force believes that the addition of this provision will not only assist permit holders in evaluating and providing the level of assistance necessary for employee pharmacists practicing in various settings, but will also allow employee pharmacists to report to the Board situations in which adequate assistance is not provided by the permit holder. The result of the provision is that errors which could be costly in terms of injury and expense to the patient can be avoided through the incurring of reasonable costs for the provision of adequate pharmacy personnel by pharmacy permit holders. This provision enables a standard and mechanism for grievances without establishing restrictive quotas or ratios.

Recommendation on Problem Prescribers and Patients

A provision clarifying the pharmacist's duty to exercise independent professional judgment in determining whether to fill a prescription will be recommended for inclusion in the Pharmacy Practice Act. As a matter of professional ethics and courtesy, the decision not to fill a prescription should be made only after the pharmacist has discussed the situation with both the patient and the prescriber and after the best interests of the patient have been carefully considered.

It is the position of the Board and the Task Force that as a prescription drug specialist, a pharmacist has a responsibility to discuss with both the patient and the necessary additions and changes needed to remain current with state of the act pharmacy practice. The Task Force made recommendations in six areas: professional judgement, pharmacist workload, the pharmacist's responsibilities for patient receiving controlled substances, non resident pharmacy, assistance in the medication distribution process, and scope of practice. A summary of the Board and Task Force recommendations follows.

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It is the position of the Board and the Task Force that as a prescription drug specialist, a pharmacist has a responsibility to discuss with both the patient and the prescriber any therapy which is potentially excessive or inappropriate. The patient who is not addicted appreciates this intervention, and the prescriber who is appropriately monitoring the

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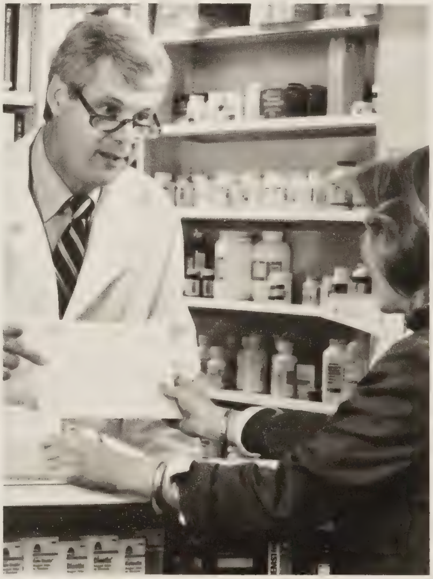

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influenza vaccinations, wound care, and blood pressure and glucose monitoring, but who do not have insurance to pay for such care and who have no regular provider of health care. Pharmacists are easily accessible to members of the public and could provide such services at reasonable costs thus reducing the need for emergency room visits and improving health care outcomes and the long term health status of the community.

Members of the Board and the Task Force recommend changes within the scope of practice that do not require pharmacists to remain or be present in the physical pharmacy setting. The intent of the change is to promote the delivery of pharmaceutical care services where they are needed. Pharmaceutical care including services such as: counseling a patient, reviewing medical records, and consulting with physicians, nurses and other integral members of the health care team on the appropriate course of pharmaceutical therapy. Changing policy to enable pharmacists to move about freely in the health care setting will enhance access to pharmaceutical care, and ensure the appropriate type and dosage of medication is administered to patients. Members of the Board and the Task Force recommend changes to the statute pertaining to the refilling of prescriptions. Pharmacists maintain patient profiles in order to monitor patients' disease states and related courses of drug therapy. This proposed change in the Pharmacy Practice Act would authorize the pharmacist to exercise appropriate professional judgement and refill prescriptions without receipt of authorization from the original prescriber. The pharmacist would be required to document that authorization was obtained from the presccriber within 72 hours of refilling the prescription.

The pharmacist providing more extensive pharmaceutical care will gain access to more medical records. The information contained in medical records is confidential. The Board must have a means for assuring that the confidentiality of medical records is preserved. Consequently, it is recommended that the violation of patient confidentiality by a pharmacist be included as grounds for discipline.

Finally, the Task Force recommendations provide for the information of one or more pharmacist peer review committees to assist the Board in evaluating possible violations of the Pharmacy Practice Act involving practice settings unfamiliar to the Board. As the profession of pharmacy expands, and practitioners are permitted to practice pharmacy in an increasing number of settings, the additional insight provided to the Board by peer review committees will permit the Board to function more efficiently aand fairly in matters of discipline.

Maryland State Board of Pharmacy
Task Force on the Future of Pharmacy Practice

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David Miller, R.Ph. former Executive Director, Maryland Pharmacists Association for drafting assistance.

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Solving the Herbal Mystery

by Clare Hasler, Ph.D., Director of Functional Foods,
University of Illinois
Herbal Consultant, Leiner Health Products

It's the fastest growing category in drug stores today and a new survey says it's about to grow more rapidly. Over 60 percent of consumers queried by Opinion Research Corporation said that herbal supplements will be "the answer to many common ailments" or "part of our daily regiment" within five years.

Given the increasingly high cost of health care and the resulting shift in focus from treating diseases to preventing them, it's a small wonder that sales of herbal supplements are white hot.

And why not? Herbs are routinely prescribed by European doctors to treat insomnia, colds, heart problems, constipation, depression and more. Fans of herbal supplements say that Americans are just waking up to what the rest of the world already knows - that herbal supplements are a natural, safer, less expensive ans sometimes more effective alternative to drugs.

Not surprisingly, the number of herbal supplement products available through the mass market is skyrocketing, making it tough for retailers and pharmacists to keep pace with their customers' questions.

If you've ever had cause to wonder who might benefit from a dose of Ginkgo Biloba - or why anyone would want to - the following information is for you!

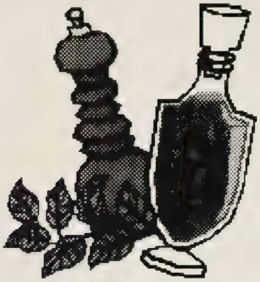
Chamomile: Used as a mild sedative and to treat digestive disorders, menstrual cramps, various skin conditions and minor infections. Used in bathwater for skin care and to treat yeast infections. Clinical trials show chamomile to be effective against inflammations and spasms in the digestive tract. Can cause allergic reactions in rare cases; otherwise, considered safe.

Echinacea: In the 19th century, echinacea was the most widely used drug in the United States. Today, in Europe, echinacea is widely prescribed as a preventive agent against colds, flu and upper respiratory conditions. Anecdotal and clinical information widely supports the immune-enhancing benefits of echinacea. In fact, Dr. Varro Tyler, a pharmacognosist at Purdue University, says it's better to take echinacea to lessen flu symptoms than antibiotics, which can be worthless against viral illnesses.

Fewerfew: Clinical studies indicate feverfew can relieve migraine pain. In addition to migraine prevention, this herb is commonly used for arthritis, menstrual irregularities, stomachache and fever.

Garlic: Clinical studies strongly support garlic's ability to lower cholesterol. Evidence also suggests garlic can fight bacteria, lower high blood pressure, prevent blood clots and protect against certain cancers.

Ginger: Used to prevent nausea and aid digestion. Some clinical studies indicate ginger is effective against



motion sickness, morning sickness and postoperative nausea.

Ginkgo Biloba: Made from the world's oldest living species of tree, Ginkgo Biloba extract is the most frequently prescribed herbal medicine by both doctors and pharmacists worldwide. It is widely used in Europe as a conventional drug for treating short-term memory loss, headache, tinnitus and depression. It's also used as an antioxidant. Claims are backed by numerous clinical trials, including a 1989 study that found Ginkgo Biloba may be helpful in some cases of senility. It is extremely safe and side effects are uncommon. Dosage: 40 mg three times daily (standardized to flavone glycodies).

Ginseng: Has been used medicinally for over 5000 years in China, Tibet and Korea, where it has been prescribed for the prevention of aging, fatigue, headaches, diabetes, and diseases of the liver, heart and kidneys. Ginseng can improve mental performance and is reputed to build physical endurance; alertness, harmonious balance and overall well-being. Numerous studies indicate that it spares glucose utilization and increases free fatty acid usage, as well as improves oxygen uptake. Studies also indicate it enhances mental performance parameters.
In one clinical study of 50 male sports teachers, maximal oxygen uptake was significantly higher, while oxygen consumption, plasma lactate levels, ventilation, carbon dioxide production and heart rate during exercise were significantly lower after ginseng supplementation compared to the placebo.

Goldenseal: The medicinal value of goldenseal derives from its high alkaloid content. Alkaloids are known to have antibacterial properties that may be beneficial in the treatment of upper respiratory tract infections. Goldenseal also is beneficial as a mouthwash to relieve canker sores. Dosage: powdered dry extract 250 to 500 mg (standardized for alkaloid content). Goldenseal should not be taken during pregnancy.

Saw Palmetto: Commonly prescribed in Europe to treat a number of male-related health problems including enlarged prostate. Human clinical trials have demonstrated the effectiveness and safety of saw palmetto extract therapy for the treatment of enlarged prostrate. It is nontoxic at therapeutic doses of up to 320 mg/day. Because of its potential hormonal effects, saw palmetto should not be used by pregnant women or those of childbearing potential.

Valerian: Numerous studies substantiate Valerian's mild sedative properties. Used as a sedative and to treat mild nervous disorders for more than 200 years, it's a popular traditional remedy for insomnia, anxiety and intestinal cramping. It is regarded as safe and is approved for food use by the U.S. Food and Drug Administration. When taking Valerian, normal reaction capability can be so far altered that driving ability and the ability to operate machinery may be impaired. As with other sedatives, this impaired ability is heightened when Valerian is taken with alcohol. Dosage 150 to 300 mg (standardized for valeric acid).

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Johns Hopkins
MEDICAL INSTITUTIONS

UPDATE IN HIV 1996

SUNDAY, OCTOBER 27, 1996

Renaissance Harborplace Hotel
Baltimore, Maryland

COURSE DESCRIPTION

This course, designed for family practitioners, internists, physician assistants, nurse practitioners, pharmacists and other health professionals, will provide updated information on the new techniques and pharmacologic interventions that are constantly emerging to better manage HIV disease.

COURSE OBJECTIVES

At the end of the program, participants should be able to:

- ✦ Identify most current management strategies for the patient with HIV;
- ✦ Identify factors that influence the cost of therapeutic management of HIV disease;
- ✦ Understand commonly encountered drug interactions in HIV regimens;
- ✦ Understand how to manage tuberculosis more effectively and identify patients at risk for tuberculosis

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PROGRAM

SUNDAY, OCTOBER 27, 1996

8:00 – 8:30 a.m.	Registration
8:35 – 9:35 a.m.	**Current H.I.V. Therapy Update** Joel E. Gallant, M.D.
9:35 – 9:45 a.m.	Refreshment Break
9:45 – 10:45 a.m.	**Management of Tuberculosis** Richard E. Chaisson, M.D.
10:45 – 10:55 a.m.	Break
10:55 – 11:55 a.m.	**Common Drug Interactions in H.I.V. Therapeutic Regimens** Charles Flexner, M.D.
11:55 – 12:00 p.m.	Break
12:00 – 1:00 p.m.	**Treating the H.I.V. Infected Patient in the Era of Managed Care** Richard Moore, M.D.
1:00 – 2:00 p.m.	Lunch and Evaluations with Faculty

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Richard E. Chaisson, M.D.
Associate Professor of Medicine, of
Epidemiology and of International Health
Director, AIDS Services

Charles Flexner, M.D.
Assistant Professor of Clinical Pharmacology,
of Pharmacology and Molecular Sciences,
and of International Health
Assistant Director, Graduate Training Program
in Clinical Investigation

Joel E. Gallant, M.D.
Assistant Professor of Medicine
Director, Johns Hopkins Outpatient HIV Clinic

Richard Moore, M.D.
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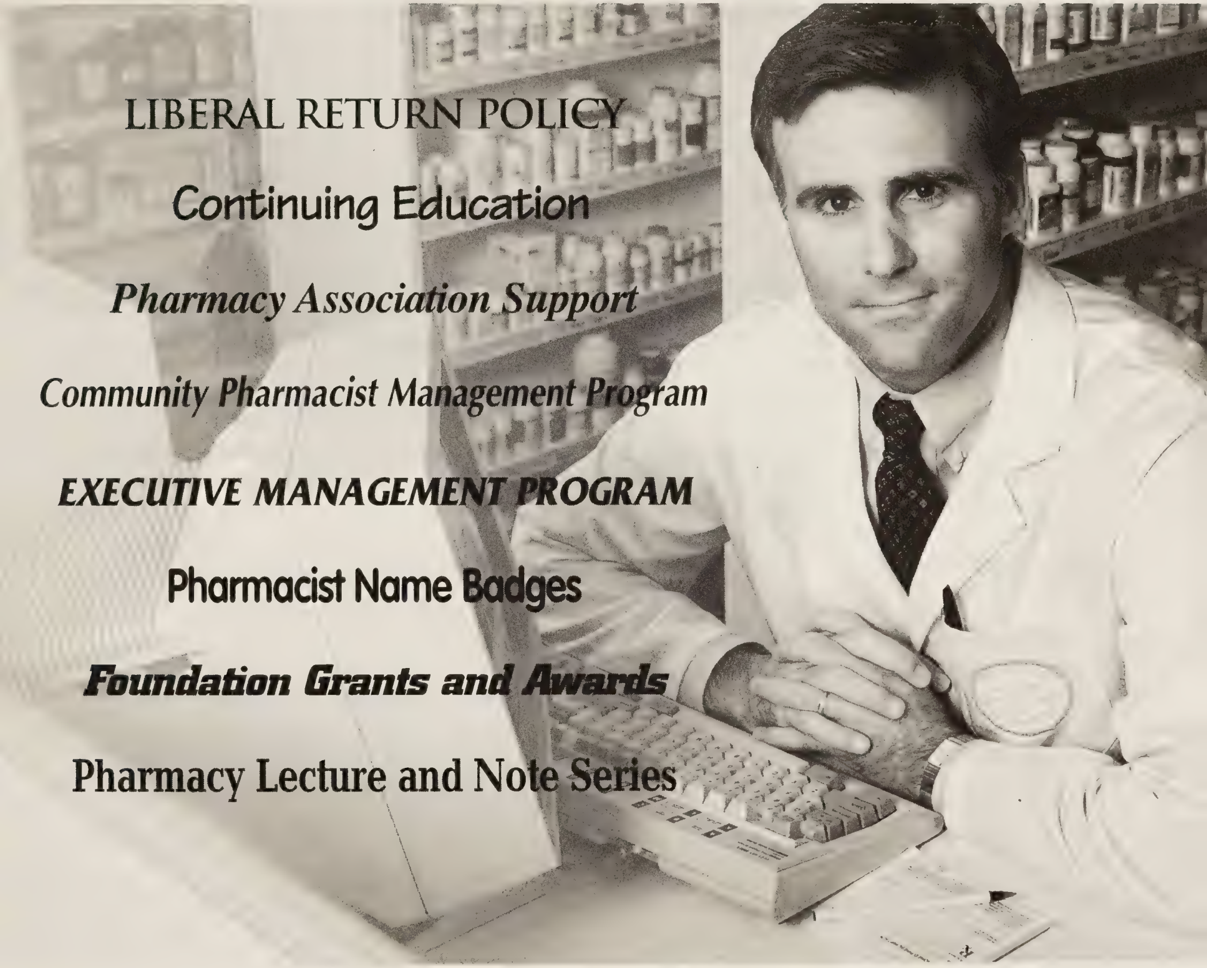

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NEW DRUGS IN BRIEF . . .*

Trade Name: Remeron

Generic Name: Mirtazapine

Dosage Forms: 15mg and 30 mg Tablets

Therapeutic Category: Antidepressant

Mechanism of Action: Acts as an antagonist at central presynaptic alpha-2 adrenergic inhibitory autoreceptors and heteroreceptors, believed to result in an increase in centralnoradrenergic and serotonergic activity..

Pre-dispensing Notes: Effective dose range usually 15mg to 45 mg daily, titrated from 15mg daily; dose reduced by 30% in hepatic and moderate to severe renal impairment; wait at least 14 days after MAOI therapy prior to initiation

Precautions: Somnolence; increased appetite and/or weight gain; increase in cholesterol/triglycerides; traminase elevations; activation of mania/hypomania; suicide precautions; no controlled studies in seizure-prone patients; Agranulocytosis; MAOI therapy

Drug Interactions: Drugs affecting hepatic metabolism; drugs metabolized by and/or inhibiting cytochrome P450; alcohol; diazepam

Contraindications: Hypersensitivity

Therapeutic Advantages: Decreased incidence of serotonergic side effects; decreased incidence of classic anticholinergic and cardiovascular effect; relatively safe in overdoses

Trade Name: Epivir

Generic Name: Lamivudine

Dosage Forms: Oral Solution 10mg/ml; Film-coated Tablets 150mg

Therapeutic Category: Antiviral

Mechanism of Action: Virustatic effect due to reverse transcriptase inhibition; inhibits replication of human retroviruses by interfering with viral RNA-directed DNA polymerase (reverse transcriptase) following conversion to a pharmacologically active metabolite.

Spectrum: Active against HIV-1, HIV-2, human hepatitis B virus

Resistance: In vitro resistance has emerged during therapy; some zidovidine-resistant HIV-1 strains are susceptible, others are resistant to both zidividine and lamivudine

Pre-dispensing Notes: Bioavailability of oral tablets and oral solution in adult HIV patients appears to be the same; dosage based on weight and age; approved for use in infants and children

Dosage in Renal Impairment: Elimination may be reduced in renal impairment, dosage should be decreased in patients 16 years of age or older with reduced creatinine clearance (50ml/minute or less); effect of renal impairment in children less than 16 unknown

* INFORMATION CONTAINED IN NEW DRUGS IN BRIEF IS FOR EDUCATIONAL PURPOSES ONLY AND SHOULD NOT BE CONSIDERED ALL-INCLUSIVE. MPHA IS NOT RESPONSIBLE FOR RELIANCE ON THIS INFORMATION. ALWAYS READ MANUFACTURER LITERATURE PRIOR TO DISPENSING.

Trade Name: Corvert

Generic Name: Ibutilide Fumarate

Dosage Form: Injection for intravenous infusion, 0.1mg/ml

Therapeutic Category: Class III Antiarrhythmic Agent

Mechanism of Action: Prolongs repolarization of cardiac tissue by prolonging the action potential duration and effective refractory period in both atrial and ventricular cardiac tissue, thought to result at least in part from activation of a slow, predominantly sodium, inward current at very low concentrations, and/or from inhibition of the rapidly activating component of the potassium channel involved in repolarization of cardiac cells at higher concentrations

Pre-dispensing Notes: May be administered undiluted or diluted 10ml ibutilide in 50ml 0.9% NaCl or D5W, resulting in a final ibutilide concentration of 0.017mg/ml

Precautions: May cause potentially fatal arrhythmias, particularly sustained polymorphic ventricular tachycardia, usually associated with QT prolongation (ie. torsades pointes), but occasionally without documented QT prolongation; administration must occur in a setting with continuous ECG monitoring by trained personnel; effectiveness not determined in arrhythmias of more than 90 days duration

Dosage: For acute management of recent-onset atrial flutter or fibrillation in adults weighing at least 60kg, 1mg ibutilide is given initially; adults weighing less than 60kg should receive an initial dose of 0.01mg/kg

Trade Name: Gemzar

Generic Name: Gemcitabine Hydrochloride

Dosage Form: Injection for intravenous infusion, 200mg and 1gm vials

Therapeutic Category: Antineoplastic Agent

Mechanism of Action: Gemcitadine is cell-cycle specific, acting principally in the S phase of the cell cycle; it may also cause cellular arrest at the G_1 - S border; cytotoxic effect attributed to the combined actions of the diphosphate and triphosphate nucleosides, which lead to the inhibition of DNA synthesis

Pre-dispensing Notes: Used for patients the palliative treatment of locally advanced (nonresectable stage II or III) or metastatic (stage IV) adenocarcinoma of the pancreas; may either be used as first line therapy or as second line therapy in patients previously treated with fluorouracil

Dosage: Usual recommended dosage in either chemotherapy naive patients or when used as second-line therapy is 1g /m^2 once weekly; initial treatment cycle lasts as long as tolerated, up to 7 weeks, followed by a week of rest from treatment

Administration: Vials should be reconstituted by adding 5ml and 25ml (200mg and 1gm vials, respectively) of 0.09% NaCl, shake to dissolve; additional dilution is not necessary, reconstituted solutions should be infused IV over 30 minutes

Precautions: Infusion for longer than 30 minutes is associated with a prolonged half-life and increased toxicity; infusion time should *never* exceed 60 minutes

Trade Name: Helidac Therapy

Content of a Therapy Kit: 112 bismuth subsalicylate 262.4mg chewable tablets, 56 metronidazole 250mg tablets, USP, and 56 tetracycline hydrochloride 500mg capsules, USP, for oral administration for 14 days

Mechanism of Action: *Helicobacter pylori* (H. pylori) is associated with an estimated 80% of all gastric ulcers and with nearly 100% of all with duodenal ulcers. H. pylori secretes the enzyme urease, which allows the bacteria to survive for years in the stomach, undetected. The combination of bismuth subsalicylate, metronidazole, and tetracycline has been proven effective in eradicating H. pylori, which is associated with high levels of ulcer recurrence.

Indications and Usage: To be used in combination with an H_2 antagonist for the treatment of patients with an active duodenal ulcer associated with H. pylori infection.

Pre-dispensing Notes: Bismuth subsalicylate should not be administered to children and teenagers who have or who are recovering from chicken pox, to avoid precipitation of Reye's syndrome. Metronidazole has been proven to be carcinogenic in mice and rats. Use of tetracycline during the last half of pregnancy and in children up to the age of eight causes permanent tooth discoloration, and enamel hypoplasia. Screen patients for these conditions prior to dispensing.

Precautions: Bismuth subsalicylate has been shown to cause a temporary, harmless darkening of stools. Metronidazole should not be used in patients with severe hepatic disease or with evidence of or history of blood dyscrasias; avoid alcohol. Superinfection can occur with the administration of tetracycline.

Drug Interactions: Those associated with the components of the Therapy Kit.

Dosage Regimen: Bismuth subsalicylate 525mg, metronidazole 250mg, and tetracycline 500mg four times daily. Doses should be taken at meals and at bedtime with food. H_2 antagonist as directed.

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Continuing Education for Pharmacists - Patient Counseling: Self-Treatment of Heartburn, Part 1: The Conditions

Thomas A. Gossel, R.Ph., Ph.D., Dean, and Professor of Pharmacology and Toxicology, Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph., Pharm.D.
Professor of Pharmacy Practice, University of Cincinnati
Cincinnati, Ohio .

Goals

The goals of this lesson are to discuss heartburn, sour stomach and acid indigestion, and present information to use when counseling patients on these conditions. Throughout this lesson, these symptoms will be referred to collectively as *heartburn*.

Objectives

At the conclusion of this lesson, successful participants should be able to:

1. select the clinical features and etiology of heartburn;
2. choose from a list, the factors that aggravate heartburn;
3. identify diseases and/or conditions that may cause symptoms which require professional attention;
4. choose the nonpharmaccolic means to treat heartburn; and,
5. demonstrate the ability to counsel patients on the uses and prevention of heartburn.

The switch of Histamine-2 receptor antagonists (H_2 blockers) from prescription to OTC status, allowing Americans to self-treat heartburn, sour stomach, and acid indigestion, has triggered renewed interest in their use to treat these common disorders. This lesson discusses the etiology of heartburn. Part 2 expands the topic and discusses the role of drugs, including self-treatment with the H_2 blockers.

A professional development program made possible by an educational grant from

SEARLE

Background

Millions of Americans periodically periodically suffer from heartburn. Ten percent of adults in the U. S. reportedly suffer from symptoms each day, and at least 30 percent experience them once a week or more often.

Over-the-counter (OTC) products have been popular remedies and widely used for many years to treat heartburn. They are safe and effective when used correctly. In recent years, such products have been limited primarily to antacids and antacid/alginic acid preparations. A third treatment option, low-dose H_2 blockers (Table 1), is now possible. Like their predecessors, these H_2 blockers are also safe and effective for their intended use.

Heartburn

Heartburn (pyrosis) is best defined as a painful, burning sensation in the lower chest that radiates upward toward the neck. Patients often indicate this with an upward movement of their hand from the stomach to the sternum (breastbone) area. Heartburn is characterized by waxing and waning episodes, worsened by reclining or bending, and relieved by standing, drinking fluids, or repeated swallowing. It is more common following a meal. It may also be associated with a bitter taste in the mouth. Some individuals may describe a condition they call "sour stomach," or a feeling of fullness or bloating. The discomfort of heartburn can be accompanied by belching, nausea, loss of appetite, and regurgitation of food.

The intensity of symptoms can vary greatly from person to person. Some experience little more than mild discomfort that is not

Table 1

H_2-Receptor Antagonist Products for Self-Treatment of Heartburn, Sour Stomach and Acid Indigestion[1]

GenericName	Trade Name	Indication(s)	Dose
Cimetidine	Tagamet HB[2]	Relief of heartburn, acid indigestion and sour stomach	Two tablets (200 mg) with water as symptoms occur or as directed by a doctor, for a maximum dose of 4 tablets in 24 hours.
Famotidine	Pepcid AC[2] 10mg tablets	Relief of heartburn, acid indigestion and sour stomach	One tablet (10mg) with water as symptoms occur or as directed.
		Prevention of these symptoms brought on by consuming food and beverages	One tablet one hour before eating a meal expected to cause symptoms, for a maximum dose of 2 tablets in 24 hours.

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1. At the time of preparation of this lesson, OTC versions of Zantac and Axid had been approved for switch to OTC status.
2 HB = Heartburn; AC = Acid Controller

Table 2

Potentially Serious Disorders That Can Mimic Heartburn

- Asthma
- Benign or malignant pancreatic disease
- Coronary ischemia
- Esophagitis
- Gallstones
- Gastric malignancies
- Gastritis or duodenitis
- Peptic ulcer disease

accompanied by other symptoms. Others may suffer persistent, debilitating pain. Patients with severe and unrelenting heartburn, especially that which does not respond to self-treatment with OTC products, should be referred to a physician for professional assessment and follow up. A list of potentially serious disorders that may be mistaken for heartburn is presented in Table 2.

Heartburn is particularly common during pregnancy and connectivetissue disorders such as scleroderma. The most common cause is gastroesophageal reflux disease (GERD), or regurgitation of gastric contents into the esophagus. Symptoms resembling GERD may mimic a more serious disorder such as peptic ulcer disease or gastric malignancy. Persons with GERD who also have concomitant symptoms such as difficulty in swallowing (dysphagia), coughing, wheezing, hoarseness, gastrointestinal bleeding, chest pain and dental erosion and/or caries should be referred to a physician. The same warning holds when symptoms are particularly severe, persistent or recurring, or heartburn fails to respond to recommended doses of OTC therapy.

Physiologic Basis for Heartburn

Hydrogen ions (acid) are secreted into the stomach lumen in response to stimulation of gastric parietal cells by acetylcholine, gastrin, and histamine. These endogenous chemicals are released when food enters the stomach. They stimulate gastric acid secretion by first binding with receptors located on the membrane of parietal cells. These cells are found primarily in the upper half of the stomach, but also occur in the lower portion. Their function is to secrete hydrochloric acid into the stomach lumen.

The stomach is normally protected from the potentially corrosive action of gastric juices by the mucus layer and bicarbonate ions. This combination, along with the mucosal blood flow which provides nutrients and removes waste products of metabolism and normal cell renewal, protects and preserves the integrity of the gastric mucosa.

The esophagus is also lined with a layer of mucus. However, there is far less mucus available so its defense against gastric juices is limited, making it more vulnerable to attack by acid and stomach contents. Therefore, when the gastric contents are refluxed into the esophagus, they stimulate nerve endings and patients complain of pain or burning (i.e., heartburn).

Etiology of GERD

GERD is a distressing problem. It can result from several factors: abnormal functioning (incompetency) of the lower esophageal sphincter (LES), abnormal esophageal clearance and gastric emptying, and direct irritation by the refluxed gastric contents (e.g., acid, bile, pepsin).

Incompetent LES. The LES is a circular muscle bundle located at the distal one to two inches (lowest portion) of the esophagus. It regulates passage of solids and fluids from the esophagus into the stomach. The entrance of the esophagus into the stomach is at an oblique angle (i.e., neither perpendicular nor parallel to the vertical line of the esophagus) which aids the LES in preventing gastroesophageal reflux.

The LES is not a true anatomical sphincter because the cells that comprise it are not histologically different from surrounding tissue. It does not contract totally shut as do other sphincters. Moreover, it is stimulated, rather than relaxed, by cholinergic, i.e., acetylcholine, innervation via the vagus nerve. The LES relaxes in response to swallowing, which permits ingested food to pass into the stomach. It then narrows to prevent reflux of the gastric contents into the esophagus.

There is no overriding explanation as to why the LES may fail to prevent reflux of gastric contents. Studies have established that transient decreases in LES tone occur normally. In most people, a quick peristaltic wave pushes the refluxed material back into the stomach before it causes significant discomfort or damage. If acidic material remains within the esophagus, it is quickly neutralized by the bicarbonate ions contained in swallowed saliva. If the muscle tone of the LES is inadequate to prohibit reflux, heartburn may be the outcome. An insufficient LES tone is one cause of reflux. Inappropriate relaxation of a normal LES, i.e., relaxation not triggered by swallowing, is associated more commonly with reflux. While it is unclear why the LES becomes incompetent, the contributing factors are much better defined. These include any activity and substance that reduce the LES pressure and/or increase the intra abdominal pressure. These are described later.

Abnormal Peristalsis. The esophagus is normally cleared of gastric contents by peristaltic contractions and, as stated above, any remaining acidic gastric contents are neutralized by bicarbonate in swallowed saliva. Pathologies or abnormalities that reduce motility and/or salivary flow can result in delay esophageal clearance. This, in turn, may prolong the contact time between the esophageal mucosal lining with gastric acid. It is the irritation by gastric acid on the mucosal lining that induces heartburn and the potential esophageal damage.

Impaired Gastric Emptying. Heartburn can result from impaired gastric emptying. Delayed gastric emptying may increase the intraabdominal pressure which, in turn, increases the likelihood of reflux, especially following a meal.

The mechanisms just described contribute to the etiology of GERD and its primary symptom, heartburn. In each case, it is the contact of gastric acid with pain receptors in the esophageal mucosa that causes the symptom. Other substances in the gastric contents including bile, pancreatic juice, and pepsin, increase the corrosive action.

Other Causes. Heartburn may also result from organic disorders such as gastric malignancy. Continuous heartburn for longer than two weeks point out the possibilities of more serious pathology.

Factors that Aggravate Heartburn

It was once believed that hiatal hernia, protrusion of the segment of the stomach wall through the diaphragm to form a pouch in the thoracic cavity, was the cause of GERD and a major contributor to onset of heartburn. Today, the role of hiatal hernia in GERD is controversial. It is known that hiatal hernia does not cause GERD, although a reported 95 percent of patients with GERD also have a hiatal hernia. A contemporary theory is that a hiatal hernia actually serves as a reservoir for acid reflux into the esophagus.

The factors (Table 3) that stimulate gastric acid production, reduce acid clearance, increase the intraabdominal pressure, or decrease the LES tone can aggravate heartburn. Since gravity facilitates the movement of substances downward through the esophagus, a person's posture plays a major role in the incidence of heartburn. Reclining can further potentiate the chance for heartburn by enhancing the leakage of acid through the LES into the esophagus.

Moreover, reclining causes the organs in the abdominal cavity to redistribute, which can increase the intraabdominal pressure. This, in turn, can force the LES to relax, and permit reflux of gastric contents into the esophagus. Gastric distention from overeating, bending at the waist, wearing tight clothing, or from consuming gas-

Table 3

Factors That Affect Lower Esophageal Sphincter Pressure

	Raise LES Pressure	Lower LES Pressure
Foods:	carbohydrates, proteins	chocolate, fats, peppermint, spearmint
Drugs:	alpha-adrenergic agonists, beta adrenergic blockers, cholinergics, metoclopramide, anticholinesterases	alpha-adrenergic blockers, beta-adrenergic agonists, anticholinergics, theophylline, nitrates, progesterone, papaverine, dipyridamole, calcium channel blockers, benzodiazepines, narcotics
Other substances:		caffeine, nicotine, alcohol
Physiologic factors:	serotonin, prostaglandin $F_{2\text{alpha}}$ histamine, high gastric pH, increased intraabdominal pressure	dopamine; prostaglandin E_1, E_2, A_2; acetylcholine; low gastric pH; cholecystokinin and other GI hormones

producing foods and beverages can also lead to increased intraabdominal pressure and gastric reflux.

The LES pressure may be decreased by particular foods, including fats, chocolate, peppermint and spearamint. A variety of drugs have been identified that lower the pressure. These are listed in Table 3.

Certain foods and beverages may irritate the stomach that can, in turn, aggravate heartburn and acid indigestion. These include coffee (both caffeinated and decaffeinated), other caffeinated beverages, citrus juices, tomatoes, high-fat foods, and spicy foods. Eating large meals can also contribute to these symptoms.

Alcohol and cigarette smoking lower the LES pressure and stimulate secretion of gastric acid. Nicotine also reduces the body's natural defense mechanisms that protect the stomach lining from damage caused by gastric juices.

Nonpharmacologic Management of Heartburn

Several nonpharmacologic approaches to management of symptoms are recommended for patients with mild reflux-induced heartburn. These measures generally involve alterations in behavior, dietary intake, or lifestyle, and are directed at eliminating the aggravating factors mentioned previously.

If the patient is obese, weight loss will reduce intraabdominal pressure. This may be sufficient to control symptoms in a significant number of patients. Relief may be obtained by eating smaller meals. Bending at the knees, rather than at the waist, helps reduce intra-abdominal pressure and the likelihood of reflux. Wearing suspenders, rather than a belt, may be more comfortable.

Individuals should avoid lying down for a least two hours after eating to facilitate esophageal clearance. Large meals should be eaten earlier in the day with smaller ones in the evening. The evening meal should be eaten at least three hours before bedtime. Bedtime snacks should be avoided.

Exercise should be avoided after meals. Exercise increases intraabdominal pressure, thus inciting reflux.

Symptoms that occur when the person is lying down can often be prevented by elevating the head of the bed about six inches. This is preferred over using a hospital bed because the latter bends in the middle, this increasing the intra-abdominal pressure of a person lying in one. Some authorities recommend that affected persons lie on a foam wedge. However, foam wedges are not appropriate for everyone because they also force the individual to bend slightly at the waist.

Avoiding or reducing alcohol and tobacco use, as well as foods and drugs that reduce the LES pressure, and those that are known to irritate the gastroesophageal mucosa, should help prevent heartburn. Chewing gum or sucking on a sugarless hard candy can also enhance esophageal clearance by increasing salivary flow.

Pharmacologic Treatment

OTC pharmacologic therapy for heartburn, sour stomach and acid indigestion includes antacids and antacids/alginic acid combinations. Recently, low-dose H_2 blockers for self-treatment have become available. These OTC products form the basis for Part 2 of this series.

Counseling Patients With Heartburn

Most persons seek the counsel of a pharmacist before a physician when suffering from heartburn, or other vague symptoms of gastric distress. This, an understanding of the causes and clinical features of heartburn will assist in providing better patient care. In general, the non-pharmacologic treatment measures discussed in this lesson should be tried first. If these measures fail to relieve symptoms, or the individual cannot follow them, OTC products may be tried.

Some patients who complain of heartburn may not be candidates for OTC therapy. They may suffer from a serious underlying pathology that requires professional evaluation and treatment by a physician. These patients should be referred to a physician for appropriate follow-up.

Part 2: Self -Treatment of Heartburn

Effective products are available to self-treat symptoms such as heartburn, sour stomach and acid indigestion. These will b included in Part 2 of this series.

MphA members can receive one contact hour of CE by completing and returning the CE quiz on page 38 of this issue. This program has been approved for one credit hour (0.1 CEU's) of ACPE approved continuing education. The Maryland Continuing Education Coordinating Council is an approved provider of continuing education programs for pharmacists by the American Council on Pharmaceutical Education. ACPE # 144-999-96-016-H04

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Pharmacists in War Time: Memories of a Profession

- ***Were you a pharmacist or a pharmacy student before 1946?***
- ***Did you serve in the military or merchant marine during World War II?***
- ***Did you work in any pharmacy function as a civilian?***
- ***Did you go to pharmacy school on the G.I. Bill after the War?***
- ***Do you know someone else who did?***

If you can answer yes to any of these questions, I need your help.

"Pharmacists in War Time: Memories of a Profession" is a volunteer project to collect information from and about pharmacists during World War II. The objective is to organize and disseminate the memories of pharmacists and others who were engaged in any pharmacy services, military or civilian, during the War period.

The war years were a historical watershed in American history, including the practice of pharmacy. However, there is little contemporary history available about practice during that period. This includes the military assignments of pharmacist who were drafted or enlisted. Some served as pharmacist mates or corpsmen. Many served in other types of assignments and may or may not have practiced pharmacy on the side. Pharmacy on the home front was also a challenge.

There is little written about civilian practice activities, such as the quinine collection of 1943 and the salvage drives to reclaim tin tubes. Likewise, there are few contemporary records of how practitioners coped with the shortage of some materials and what ingenuous methods and expanded roles that they put into place to meet the needs of patients and customers.

Pharmacy education was rapidly moving to an accredited, baccalaureate program. Whole new classes of therapeutic agents, ranging from penicillin to Atabrine to blood products, emerged from the industry. New delivery systems, such as early unit dose packaging and prefilled syringes, were tested in new and harsh conditions. This all presaged many changes to how and where pharmacy would be practiced. These are insights into the profession, the practice and its practitioners that will be lost if they are not systematically collected and preserved.

This project is supported through an American Institute of the History of Pharmacy Fischelis Grant. All materials collected through this project will be deposited with American Institute of the History of Pharmacy for use in future scholarship activities.

Contact me or the MPhA offices for a survey or write me about your memories.

Dennis B. Worthen, Ph.D.
1723 Old Farm Drive - Loveland, Ohio 45140
(513) 583-5163
worthendb@aol.com

American Institute of the History of Pharmacy
1996 Fischelis Grant Recipient

Continuing Education Quiz

September/October 1996

This month`s questions are taken from the article on Patient Counseling: Self-Treatment of Heartburn, Part I: The Condition that appears in this issue. Circle your answers to the following questions and mail the entire page to Pharmacist Journal CE, 650 West Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members $ 5.00). The completed quiz for this issue must be received by October 31, 1997. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly. ACPE # 144-999-96-016-H04

Name ______________________________

Address ______________________________

City/State/Zip Code ______________________________

1. The most common cause of heartburn is:
a. achlorhydria.
b. gastroesophageal reflux disease.
c. peptic ulcer disease.
d. Zollinger-Ellison syndrome.

2. Hydrogen ions are secreted into the stomach lumen by:
a. chief cells.
b. gastric cells.
c. parietal cells.
d. reflux cells.

3. All of the following information is appropriate for counseling patients with mild heartburn EXCEPT:
a. bend at the knees rather than the waist.
b. sleep on a hospital bed rather than on a regular one.
c. try eating smaller meals.
d. avoid exercise after meals.

4. Which of the following is most likely to be used to raise LES pressure?
a. Dipyridamole
b. Metoclopramide
c. Papaverine
d. Theophylline

5. Histamine-2 blockers are indicated for self-medication of all of the following EXCEPT:
a. acid indigestion.
b. heartburn.
c. peptic ulcers.
d. sour stomach.

6. Hydrogen ions are secreted into the stomach lumen in response to stimulation by all of the following EXCEPT:
a. acetylcholine.
b. gastrin.
c. histamine.
d. serotonin.

7. Which of the following OTC histamine-2 blockers is indicated for both relief and prevention of heartburn?
a. Pepcid AC only
b. Tagamet HB only
c. Both Pepcid AC and Tagamet HB
d. Neither Pepcid AC nor Tagamet HB

8. Patients suffering from dysphagia have difficulty in:
a. breathing.
b. digesting meals.
c. maintaining balance.
d. swallowing.

9. All of the following drugs lower LES pressure EXCEPT:
a. beta blockers.
b. nitrates.
c. benzodiazepines.
d. anticholinergics.

10. The term LES refers to the:
a. circular muscle bundle in the esophagus.
b. number of hydrogen ions in the lumen of the stomach.
c. lining of mucus along the gastrointestinal tract.
d. sphincter between the stomach and the duodenum.

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A non-profit drug education and substance abuse detoxification referral service is launching a public relations campaign in the Baltimore City School System for the 1996/1997 school year. It involves a pharmacist in a city classroom one hour a week counseling children on drug education topics. If you would like to make a difference in a child's life and be part of this successful, rewarding program, please call Kemi Olunloyo, P.D., Public Relations Specialist at (410) 998-1033

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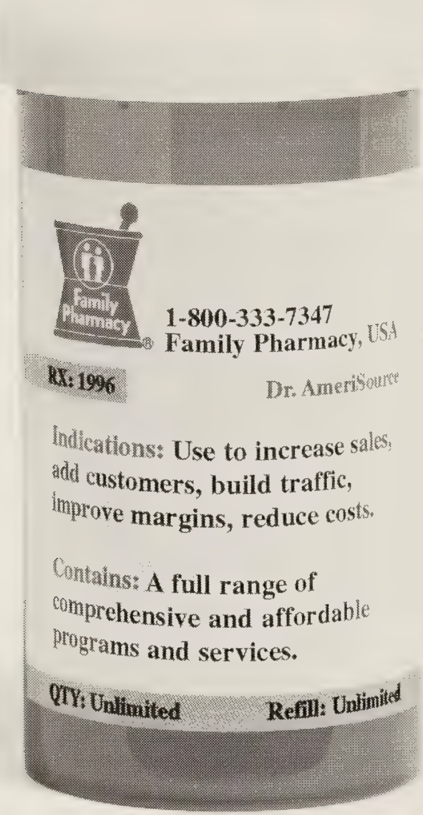
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MARYLAND Pharmacist

Volume 72, No. 6

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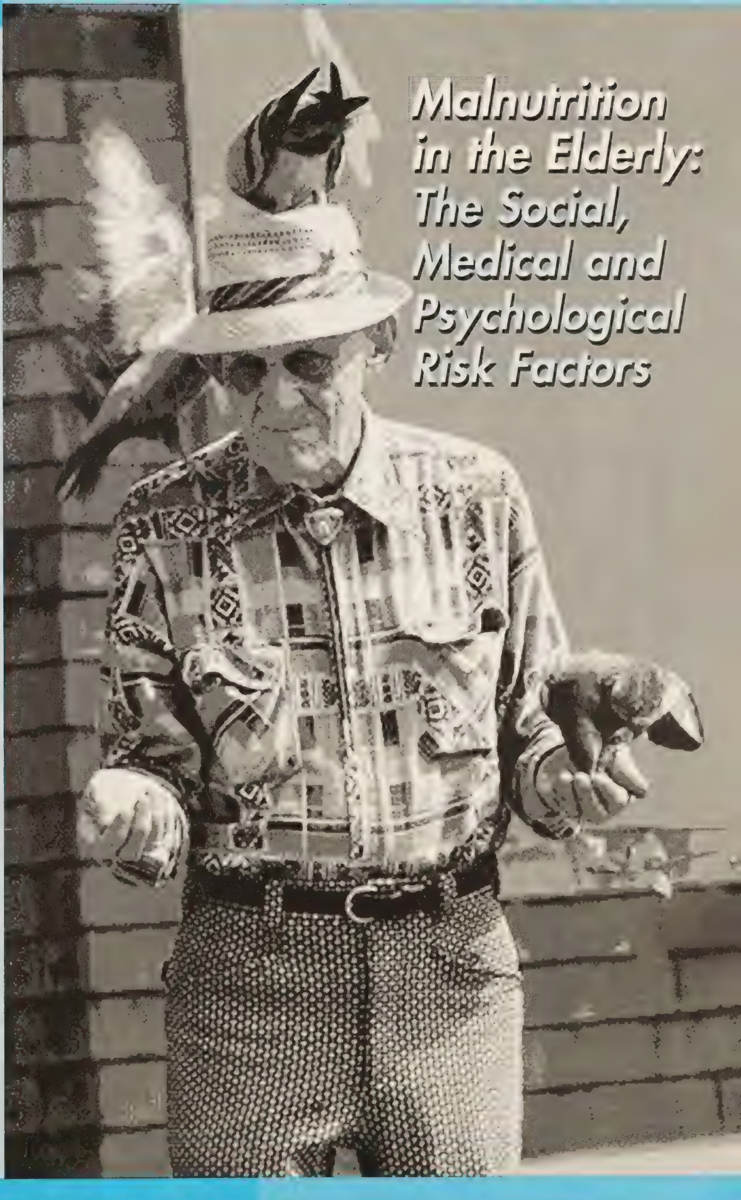
Board of Pharmacy:

New Long Term Care Regulations

President's Commentary:

Practice Act



Malnutrition in the Elderly: The Social, Medical and Psychological Risk Factors

MARYLAND PHARMACISTS ASSOCIATION November/December 1996

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President's Commentary

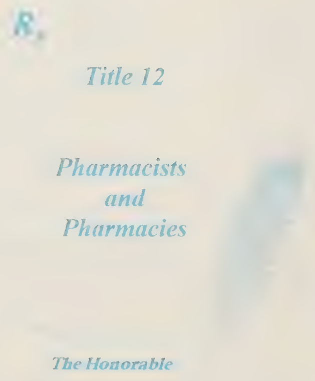
Practice Act

Ernest Testerman, P.D., President

I hope that all Maryland pharmacists have heard about the revision of the Pharmacy Practice Act of Maryland. This has been a massive pursuit by the Maryland Board of Pharmacy to update the standards of pharmacy practice for the State of Maryland. As we all know, the practice of pharmacy is continually changing; so therefore, so should the standards. This pursuit has occurred with the help of subcommittees focusing on different aspects of the profession. These subcommittees were made up of pharmacists from different practice settings, in hopes of addressing all potential concerns of the profession.

I commend those pharmacists who participated in the upgrading of the Pharmacy Practice Act. However, now that the subcommittees and the Maryland Board of Pharmacy have put the proposed new Practice Act together, I will sound the first warning bell. I recommend that every pharmacist who works in Maryland read this document and express any concerns they have to the Maryland Board of Pharmacy. The best way to express these concerns would be in written form and addressed to the Board of Pharmacy. It is important to express these concerns now before this document is submitted to the legislature for approval. This document, once approved by the legislature and signed by the Governor, will be the standards of practice for which pharmacists will be held accountable in our practice.

We need to make sure the new standards address the concerns of pharmacists who work behind the counter, those in collaborative practices, and those who manage pharmacies everyday. We need to make sure they address the issues of adequate ancillary personnel and the appropriate use of automation with the concerns of pharmacists being top priority. There needs to be concern because we will be accountable to these standards by the Board through fines and/or licensure management. Therefore, these standards need to provide the Board of Pharmacy the power to ensure that outside forces do not dictate how pharmacy is practiced on a daily basis. Let's seize the opportunity now to ensure that the revision is accomplished efficiently, concisely and fairly to all pharmacists. We have the opportunity to affect a document that will be our guide for pharmacy well into the twenty-first century, so lets not miss it through procrastination. . . . .



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Title 12

Pharmacists
and
Pharmacies

The Honorable

Interactions...

Maryland-Brand Pharmacists and the MPhA New Appointments

David A. Knapp, Dean
University of Maryland School of Pharmacy

The School of Pharmacy's graduating class of 1996 was the first of its new all Pharm.D. professional program. This re-engineered program, started in 1993, features modular courses, small group instruction, greater use of the computer and information sciences, and more emphasis on the development of critical thinking and oral and written communication skills. Competition for admission to the new program has increased dramatically and fewer than one in six applicants are admitted.

As of May, 1996, the first graduates of the new program are now in the profession. Since the true worth of an educational program can only be measured by the long term success of its graduates, it will be a generation before we *really* know whether the changes that the faculty has implemented are truly worthwhile. This long-delayed payoff is an explanation of why educational change often seems to proceed at a glacial pace and why dramatic changes such as we undertook are so unsettling to many.

But we now have the first external evidence of the success of our graduates. The results of the June, 1996 State Board of Pharmacy examinations are in. Ninety-seven percent of Maryland's class of 1996 passed the Board examination. Three quarters of the graduates exceeded the national average, and the average score of a Maryland graduate was fully *10* points above the national average and *12* points above the average of all those who took the Board exam in Maryland in June.

The national pass rate for the NABLEX exam was 89%. The state pass rate was 85%, while 97% of the University of Maryland graduates passed the exam. Thus, we have some external validation of what our faculty have known all the long; that Maryland graduates are very, very competitive, indeed.

These graduates, like any graduates, are bright, energetic, and motivated, but need mentoring if they are to develop quickly and reach their full potential. The Maryland Pharmacist Association can help. New pharmacists represent the future of the profession. MPhA has a vested interest in attracting these new graduates into the organization, so that both may grow in a profession and a health care system being churned by change.

The leadership of MPhA always works hard with students to nurture relationships and support student growth. That relationship must be continued and strengthened now that the new graduates have entered practice. This means the development of programs and services geared to the needs of new Pharm.D.

pharmacists entering the profession. After four years of being a part of a tightly-knit group, graduates are now on their own in new jobs or in some form of advanced education such as residencies. The *Maryland-brand* pharmacists of the Class of 1996 are already exhibiting their superior qualities. Now is the time for MPhA to harness their enthusiasm and talents to build an ever-stronger professional association for the future.

Senior-Level Appointments Made at School

Several senior-level appointments have been made at the University of Maryland School of Pharmacy over the past few months. These include:

Richard Rumrill, BS, MS has been appointed Director of Experiential Learning. Mr. Rumrill will be responsible for directing all phases of the doctor of pharmacy experience program and will coordinate the activities of the School's over-400 volunteer faculty. He brings to the position over 20 years of institutional pharmacy practice experience in Maryland, most recently as director of Pharmacy Services at Howard County General Hospital.

Patrick McKercher, Ph.D., is the new director of The Center on Drugs and Public Policy. Dr. McKercher joins the faculty after ten years in corporate public policy at The Upjohn Company and an earlier faculty appointment at Wayne State University. He is responsible for the interdisciplinary research center focusing on drug use.

Keith Chan, Ph.D. becomes the Assistant Director of the Pharmokinetics/Biopharmaceutics Laboratory. Dr. Chan comes to Maryland from his previous position as director of the Division Bioequivalence in the Center for Drug Evaluation and Research of the Food and Drug Administration. He brings to his position not only government experience but a good understanding of research and scientific affairs in the pharmaceutical industry.

Vivienne Lee, MA, is the School's new Director of External Affairs. In her position, Ms. Lee will be responsible for School development and fund-raising activities, liaison with the Alumni Association, and Public Affairs. Her previous experience includes work with the Center for the Advancement of Secondary Education in Washington, DC.

Sue Briggs, Ph.D. has been appointed Associated Dean for Administration. She is responsible for financial, human resources, and facilities management for the School of Pharmacy. She held a similar position at the University of Baltimore and received her Ph.D. in higher education from the University of Maryland at College Park.

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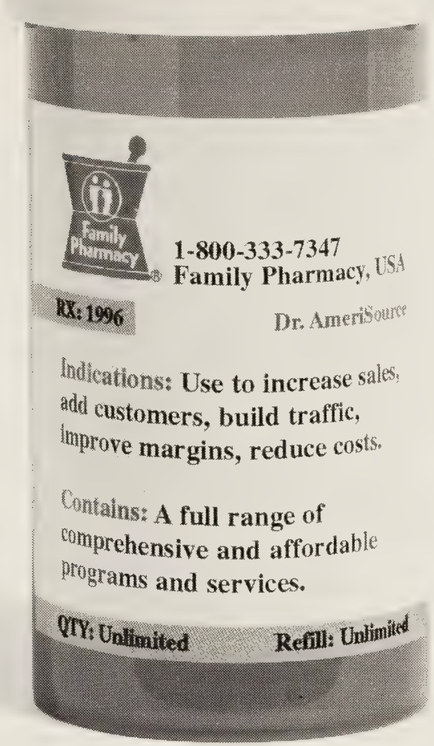
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Walk Your Talk

Tracy L. Baroni, R. Ph., J.D.
Executive Director

Nine years ago when I graduated from pharmacy school, it never occurred to me. During the time I worked in an inpatient pharmacy, I began to see it. Then, back in community pharmacy, it was gone again. When I was not practicing pharmacy, it again became evident. And now, having listened, learned, and listened some more for the past four months, there is no denying it.

What is it? It is the inevitable fact that the profession of pharmacy has cornered itself into being a product-based profession; and, therefore, is viewed not as a profession but as a business. Okay, so this is not a revelation. But it is a warning - not a flashing yellow light, but a flashing red light.

Stop - right now - and think about your practice setting. What do you spend most of your time doing? The actions and verifications involved in the prescription/order filling process, or providing drug information? Worrying and wondering whether the most recent changes in reimbursement rates are fair and adequate, or pulling prescriptions out of your will-call bin in an attempt to contact patients and increase compliance? A product is a product is a product. Whether the prescription is a generic or brand, a Merck product or not, a cash patient or not. What differs from prescription to prescription is the people behind the prescription. The prescriber, chosen by the patient for various reasons, including practice specialty, location of offices and hospital privileges, and comfort level felt. The pharmacist, chosen, overwhelmingly, *not for the pharmacist, but for the location of the pharmacy.*

So, you say you have enough patients that come to your pharmacy because it's in a good location. Or, your patients are the exception and will continue to come to your pharmacy despite the fact that it is not as convenient as others more strategically located. If this is your situation, I commend you on your ability to run a good business. But let's look at it logically. If you had to live off of the reimbursement rates you accept and cash prices you charge, would you make enough to pay a pharmacist's salary, of, say, $58,000 a year? Granted, you can add in the extras - the liquor, the tobacco products, the cards, candy and gifts. The problem with these items is that they are available other places, including places which are more convenient than your pharmacy. Few customers, even the most loyal, realize they are hurting you, their favorite pharmacist, if they purchase their lottery tickets elsewhere. What is not available elsewhere is the knowledge of a pharmacist. Pharmacy isn't about being a business anymore, it's about being a profession.

Speaking from a legal perspective, recognized professionals enjoy benefits not available to business entities or non-professionals. Professionals can legally form a P.C., or professional corporation. Professionals who are in a properly formed P.C. can provide services together, sharing costs and liability, without question as to the appropriateness of shared thoughts and information. A group of *pharmacists* can form a P.C. and apply, as a financially sound P.C., to be providers to be included in a particular health care network. A group of *pharmacies* which does this is viewed as forming an anti-competition alliance and will be investigated for violations of the FTC Antitrust Guidelines.

So, you want to snatch your profession back from the jaws of the pages of *The Maryland Business Journal*, but aren't sure where to start? After you evaluate how your time is spent in the manner described above, evaluate how you believe your time would be best spent, in the interest of continuing to be successful in your chosen profession. As an independent pharmacy owner or pharmacist, a conscious effort to provide more of what an independent pharmacy has been known for providing is the first step. Even if it means paying another pharmacist for 4 hours a day in order to spend time educating patients, even if it means taking certification classes or specialized compounding classes, or building a counseling or compounding room. As a pharmacist in a chain, begin by talking to some of your regular patients to learn whether they would be willing to pay for educational and counseling services provided by you, their pharmacist, rather than a prescriber or other health care professional. After you have an idea of the interest level, approach your supervisor and propose that 2 hours a day be allotted for pharmacist care activities. If you are an institutional pharmacist, your transition, in my view, is easier than most. If you are not already going on rounds, pick a population and request to be permitted to round. Those who are rounding, request to be responsible, under institutional protocol, for certain classes of orders - ie. parenteral/enteral nutrition, antibiotic dosing, pain management, discharge patients - based on your areas of emphasis and educational and experiential background. I have seen it work - once the prescribers trust you, they rely on you more and you gain not only responsibility but credibility as a professional. No matter what your practice setting, remember that the resistance you encounter is most likely directly proportional to the short-sightedness of those offering the resistance. It is up to you, as the professional who wants to survive to practice in the year 2000, to find creative, legal ways around the resistance.

While the provision of pharmacist care as described above is certainly legal, the changes occurring in the pharmacy profession are not spelled out in the current Pharmacy Practice Act. The majority of the current Practice Act and the Board of Pharmacy Regulations deals with the regulation of the business of pharmacy, not the regulation of pharmacists as professionals. The Revisions to the Act will permit pharmacists, even pharmacists providing services to ambulatory outpatients, to initiate and modify orders when in a collaborative agreement with a prescriber. The Revisions will also permit a pharmacist who is "available" to be out of the pharmacy, with the pharmacist still responsible for the operations of the pharmacy. While the Revisions may not protect pharmacists from "downsizing" - that is, the coming of a day when automation and non-professionals are more in demand for dispensing functions than pharmacists - it opens doors for pharmacists to recapture their identity as the *most trusted profession*, in the real sense of the word profession.

I encourage every licensed pharmacist in Maryland to make every effort to attend one of the Board of Pharmacy briefings on the Practice Act Revisions. Ask questions, make suggestions. At this point, none of the Revision is set in stone. What it is, however, is a work in progress which represents, in my opinion, the best chance pharmacy has to recover from years of abuse as a business and return victorious as a profession. If we don't stand up for our profession, who will? Now is the time - *Walk Your Talk* - or forever hold your peace (in one hand, and a counting tray in the other).

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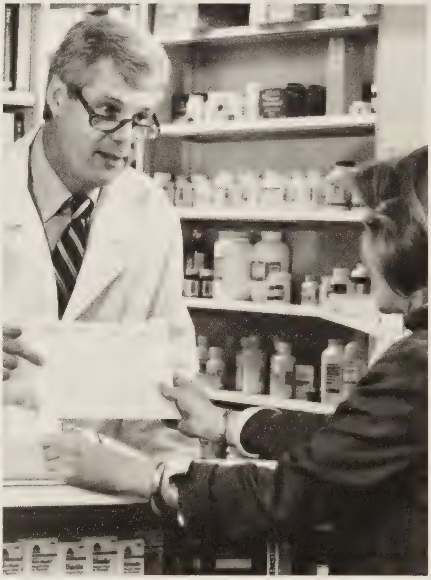

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Malnutrition in the Elderly: The Social, Medical and Psychological Risk Factors

Michael Gavin
Third Year Doctor of Pharmacy Student
University of Maryland School of Pharmacy

Nutrition is a significant determinant of health. The prevalence of malnutrition among the elderly is quite high with 10% to 15% of community-residing elderly, 20% to 60% of hospitalized elderly and up to 85% of nursing home patients showing signs of malnutrition(1). Despite the commonality of malnutrition, it is frequently overlooked by physicians. Research shows that 85% of the disease and illnesses in the elderly are nutrition related; yet, only 26% of the elderly discuss diet and/or nutrition with their physicians(2). This disorder significantly decreases the quality of life for some elderly. In addition, the high incidence of malnutrition in older patients is adding to the depletion of health care resources by causing more complications and longer hospital stays(2).

Malnutrition is a condition resulting from an excess, imbalance or deficit of nutrients available in relation to physiological needs(3). There are multiple risk factors associated with malnutrition in the elderly which can be classified into three main categories: social, psychological, and medical (Table 1). All of these risk factors can be recognized or diagnosed, and the majority of them can be prevented, treated or addressed in some way. If all health care providers, not just physicians, are trained to recognize the risk factors, malnutrition awareness will be increased and this disorder in the elderly may become less prevalent.

Table 1

SOCIAL	PSYCHOLOGICAL	MEDICAL
Impairment of ADL/IADL Low Income Social Isolation	Alcohol Anorexia Cognitive Impairment/ Dementia Depression	Chronic Disease Hospitalization Oral Health Problems Polypharmacy Sensory Impairment

I. SOCIAL RISK FACTORS

Low income is a significant risk factor for malnutrition in the elderly. The social and economic gap between the rich and the poor, which has widened in the last decade, has increased the proportion of elderly people who are nutritionally at risk(4). The income level of the elderly is often not adequate to meet basic daily needs. Elderly patients on a fixed income must often choose between buying quality food, paying their bills, or purchasing the medications prescribed by their doctor for treatment. In order to compensate, less expensive foods are purchased which are of poorer quality and nutritional content. Therefore, it is no surprise that in national surveys of food consumption patterns, intake of most vitamins and minerals were lower in adults in low-income categories compared with those in high-income categories(5).

Social isolation is another significant risk factor. People today are living longer lives than ever before. All too often it is assumed that aging and disability are directly proportional and that elderly adults at some point in their lives receive some form of supervised care. In fact, most elderly people do not live in institutional settings, but rather live at home(6). Eventually the losses of friends and family and possibly physical location all contribute to social isolation. Isolated individuals lack the appropriate mental and physical support systems. Mental support systems include social interaction. When elderly people live alone, they often do not have the desire to prepare a meal for only themselves(7). Social interaction can help to ensure adequate food intake and therefore reduce the risk of malnutrition. Physical support systems encompass transportation to and from supermarkets as well as assistance in actually preparing nutritional food. Elderly people without such support networks have a greater risk of becoming malnourished. Even those who participate in home delivered meal programs are at risk. Recipients may have certain ethnic or taste preferences that these meals do not satisfy. If these meals are foregone, there may be no other source of adequate nutrition.

Impairment in activities of daily living (ADLs) and instrumental activities of daily living (IADLs) is potentially indicative of decreased ability to perform acts necessary to support good nutritional status(5). ADLs measure basic self care activities including the ability to feed oneself. IADLs measure home management activities for independent living such as handling money and buying food or preparing a meal. An elderly person lacking in these areas may, for example, demonstrate difficulty in obtaining and preparing food for adequate nutritional sustenance. Those who are seriously impaired in these areas and need to rely on caregivers to feed them, such as patients in nursing homes or other institutional settings, are also at risk. The nutritional intake of these patients is dependent upon the time and attention the caregiver has to offer.

II. PSYCHOLOGICAL RISK FACTORS

Depression has a significant impact on the quality of life of the elderly. It can be manifested in changes in appetite, energy levels, and weight, all of which will potentially affect nutritional status. Depression may be often overlooked by physicians who believe that all elderly experience some degree of change in emotional state as they suffer through the deaths of family and friends(7).

For an elderly person mourning the death of a spouse, dining alone is a constant reminder of loneliness. As a result, some may begin to forego meals during their time of bereavement. If depression sets in, this cycle could continue unbroken. Also tied into depression is the social isolation factor. Many depressed elderly people are those living alone who have little or no motivation to cook quality, healthy meals for one.

Depression is also associated with anorexia. Distorted attitudes toward food may occur in some elderly, but the pattern of abnormalities may not be that which we would expect from classic anorexia nervosa(5). In some, anorexia has been a lifelong issue which has been brought on again by depression in older age. Others, however, are facing anorexia in their elderly years for the first time. They believe that by restricting their diets, they have a better chance at a longer more healthy life. These elderly live in the hope that dietary restriction may somehow prove to be a fountain of youth, delaying imminent mortality(7).

Cognitive impairment or dementia is frequently related to malnutrition in the elderly. Memory loss, disorientation or impaired judgment lead to difficulty in not only food preparation, but also in simply remembering to eat. Deficiencies of vitamin B12, folate, thiamine and niacin can intensify symptoms of dementia. As a result, some reversible forms of dementia may be mistakenly considered irreversible because of the effects of malnutrition(5).

If dementia finally leads to institutionalization, malnutrition becomes more probable. The risk is notably higher in elderly patients in nursing homes: 10% to 85% of older adults in long-term-care settings are malnourished(8). The average time spent feeding a demented person in their home setting is 5 to 6 times greater than in an institution(7). Therefore the institutionalized person may receive less attention and will very likely eat less. In addition, nutritional status of a patient may not be chronically monitored to detect drug-induced nutrient deficiencies(8). In addition to weight loss, cholesterol and serum albumin levels should be monitored to measure nutritional status in the elderly. A number of studies show that low serum cholesterol levels are more likely to be associated with mortality in the elderly(7). In one study, levels below 156mg/dl have been demonstrated to predict mortality in nursing home residents(7). The serum albumin level is one of the most important measures to track over time to determine nutritional status(7). Levels under 3.5g/dl indicate that the person is at risk for poor nutritional status and protein malnutrition(7).

To complicate matters further, antidepressants and antipsychotics used to treat dementia, depression and like disorders can have significant side effects which can impact nutritional status. Symptoms range from appetite changes to nausea to constipation. Chronic use of these drugs can contribute to reduced food intake and malnutrition.

Lastly is the issue of alcoholism, the extent of which may not be widely known due to the social isolation of many elderly. As a result, excessive drinking may go unnoticed. Loneliness, isolation and illness may put some elderly people at risk of alcohol abuse. And as consumption increases, the alcohol will replace meals. Vital nutrients will be lost and not replaced.

III. MEDICAL RISK FACTORS

Part of the aging process for many elderly may very well involve some degree of sensory impairment. As people age, they experience a progressive loss of taste buds predominantly on the anterior tongue that results in decreased detection of sweet and salty taste(3). This decrease in taste sensation may cause eating to become less enjoyable, and more sweet and salty foods may be taken in to compensate. Excessive intakes of this type of food will result in a poorly balanced diet. Individuals who experience difficulty with aspects of taste perception may also suffer from problems with sense of smell as well. As the sensory impairment progresses, all food begins to taste sour and bitter which can lead to decreased food intake(5). Losses of vision and hearing are associated with a decreased ability to perform ADL and IADL. As a result, buying and preparing food and eating it all become more difficult. Additionally visual impairment can effect the way a meal actually looks. If a meal does not look appealing, it may not be eaten.

Oral health problems contribute to poor nutritional status because they often physically interfere with food consumption. Loss of teeth is associated with a decrease of approximately 100 calories per day in food intake(7). Tooth loss and poorly fitting dentures limit chewing ability and consequently the types of food an elderly person is able to eat. Important sources of dietary fiber such as fruits and vegetables may be omitted(3). Elderly patients also experience lower levels of salivation which can make it more difficult to break up food and swallow while eating.

Chronically ill elderly are at high risk to develop malnutrition. They can have characteristic metabolic alterations which must be understood in order to provide them with nutritional support(9). The malnutrition risk factors in this category can be symptomatic. Eating can be extremely unpleasant because of common gastrointestinal problems such as reflux, heartburn, nausea, and diarrhea. Eating can also be physically difficult for some elderly. For example, a person suffering from chronic obstructive lung disease must increase energy intake to offset the increased work of breathing. This can lead to shortness of breath during eating, and will possibly limit food intake(3).

The risk factors can also be a result of dietary restrictions resulting from chronic disease. Diabetes mellitus, coronary artery disease, congestive heart failure and hypertension are common diseases that are accompanied by restriction of sugar, fat and salt - three dietary components predominantly responsible for the taste of food(3). Once again, a patient may choose to forego these usually bland meals.

It is important to remember that malnutrition also contributes to chronic disease states. For example, osteoporosis is accelerated by inappropriate diet including inadequate calcium intake and vitamin D deficiency(10). This condition characterized by weakened bones is believed to be the cause of many fractures in the elderly, including those of the hip and other bones. The elderly, even those with good nutritious diets, are at greater risk of calcium deficiency because their ability to absorb dietary calcium lessen over the years and becomes critical after age 70(11). Therefore just increasing calcium intake is not enough. Vitamin D is also needed to help the elderly absorb calcium since intestinal absorption is diminished with aging(12).

Chronic illnesses often lead to hospitalization where prolonged stays can put the elderly at a higher risk of malnutrition. Malnutrition in hospitals is a largely unrecognized problem much in need of attention (13). Various studies report that approximately 33% to 67% of hospitalized elderly patients are malnourished(14). There are numerous causes. In some instances patients are physically unable to eat and are placed on feeding tubes and devices which can effect nutritional intake. Others may need to rely on assistance to eat and may not receive enough attention. Still others simply may not enjoy the hospital food. The longer the stay, the more likely the elderly patient will continue to be under-nourished on a daily basis. And although a large number of elderly patients in a hospital may be malnourished, it is rarely listed by a physician as a diagnosis(2).

Polypharmacy often occurs in the elderly as a result of chronic disease and the availability of over-the-counter (OTC) medications. There are several different drug interactions that can affect nutritional status: drug-nutrient, drug-drug, drug-food and drug-alcohol.

One of the major consequences of polypharmacy in elderly patients is the risk of nutritional deficiencies induced by drugs(8). Two common drug-nutrient interactions are increased loss of sodium, potassium and calcium with loop diuretics, and decreased absorption of vitamin B_{12}, folate, iron and calcium with use of antacids or H_2 receptor blockers(3).

Many elderly combine prescription medication and common OTC medication. With an increasing number of products going OTC, there is a greater potential for drug-drug interaction that will put the elderly physically as well as nutritionally at risk. Drugs accounting for the largest percentage of potential drug-drug interactions in older adults are digoxin, oral antidiabetic agents, antacids, beta-blockers, and furosemide other diuretics(5).

Drug-food and drug-alcohol incompatibilities can often occur unnoticed but are still important to recognize. Food delays or reduces the absorption of certain OTC medications and prescriptions. Alcohol consumption affects the metabolism rate of various drugs in the system.

Because of the prevalence of malnutrition in the elderly, diagnosis, treatment and prevention of malnutrition have obvious benefits for everyone involved. They will allow for a better quality of life for the elderly which can potentially reduce health care costs related to aging. The key in accomplishing this goal is to be able to recognize the risk factors. The sole responsibility cannot fall on physicians since the elderly tend not to discuss this topic with them. All health care providers should be trained in the area of nutritional screening.

To help make this process easier, the Nutritional Screen Initiative (NSI) has developed the "Determine Your Nutritional Health Checklist" to promote awareness of malnutrition. The NSI is a collaboration of the Academy of Family Physicians, the American Dietetic Association, and the National Council on the Aging; the goal of NSI is to promote systematic nutritional screening and intervention in the health care system(15). The "Determine Checklist" (Page 16) is simple, reliable and educational, and is ideal for distribution in physicians offices, pharmacies, even health clubs or health fairs.

Pharmacists can play a prominent role in nutritional screening. It is very possible that many elderly see their pharmacist more often than their physician. While some malnutrition risk factors, such as multiple medicines, can be more readily visible to pharmacists, assessment of other risk factors can be made by having patients fill out the "Determine Checklist". Based on the information learned about the patient, the pharmacist can recommend safe and effective levels of certain nutritional supplements or offer literature or advice on relevant nutritional topics as necessary. All patient information can be kept in a patient profile so that the history is available each time a patient comes to the pharmacy for assistance.

The "Determine" evaluation along with the invaluable information the pharmacist acquires over time from patient visits can trigger awareness in elderly consumers and may encourage communication between elderly patients and their physicians. Awareness is the first step needed to diagnose, treat and prevent malnutrition in the elderly.

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Determine Your Nutritional Health

The Warning Signs of poor nutritional health are often overlooked. Use this checklist to find out if you or someone you know is at nutritional risk.

Read the statements below. Circle the number in the yes column for those that apply to you or someone you know. For each yes answer, score the number in the box. Total your nutritional score.

	Yes
I have an illness or condition that made me change the kind and/or amount of food I eat.	2
I eat fewer than 2 meals per day.	3
I eat few fruits or vegetables, or milk products.	2
I have 3 or more drinks of beer, liquor or wine almost every day.	2
I have tooth or mouth problems that make it hard for me to eat.	2
I don't always have enough money to buy the food I need.	4
I eat alone most of the time.	1
I take 3 or more different prescribed or over-the-counter drugs a day.	1
Without wanting to, I have lost or gained 10 pounds in the last 6 months.	2
I am not always physically able to shop, cook and/or feed myself.	2
Total	

Total Your Nutritional Score. If it's -

0-2	**Good!** Recheck your nutritional score in 6 months.
3-5	**Your are at moderate nutritional risk.** See what can be done to improve your eating habits and lifestyle. Your office on aging, senior nutrition program, senior citizens center or health department can help. Recheck your nutritional score in 3 months.
6 or more	**You are at high nutritional risk.** Bring this checklist the next time you see your doctor, dietitian or other qualified health or social service professional. Talk with them about any problems you may have. Ask for help to improve your nutritional health.

These materials developed and distributed by the Nutrition Screening Initiative, a project of:
American Academy of Family Physicians, The American Dietetic Association, and the National Council on the Aging, Inc.

Remember that warning signs suggest risk, but do not represent diagnosis of any condition. On the next page learn more about the Warning Signs of poor nutritional health.

The Nutrition Checklist is based on the Warning Signs described below. Use the word Determine to remind you of the Warning Signs.

Disease
Any disease, illness or chronic condition which causes you to change the way you eat, or makes it hard for you to eat, puts your nutritional health at risk. Four out of five adults have chronic diseases that are affected by diet. Confusion or memory loss that keeps getting worse is estimated to affect one out of five or more of older adults. This can make it hard to remember what, when or if you've eaten. Feeling sad or depressed, which happens to about one in eight older adults, can cause big changes in appetite, digestion, energy level, weight and well-being.

Eating Poorly
Eating too little and eating too much both lead to poor health. Eating the same foods day after day or not eating fruit, vegetables, and milk products daily will also cause poor nutritional health. One in five adults skip meals daily. Only 13% of adults eat the minimum amount of fruit and vegetables needed. One in four older adults drink too much alcohol. Many health problems become worse if you drink more than one or two alcoholic beverages per day.

Tooth Loss/Mouth Pain
A healthy mouth, teeth and gums are needed to eat. Missing, loose or rotten teeth or dentures which don't fit well or cause mouth sores make it hard to eat.

Economic Hardship
As many as 40% of older Americans have incomes of less than $ 6,000 per year. Having less--or choosing to spend less--than $ 25-30 per week for food makes it very hard to get the foods you need to stay healthy.

Reduced Social Contact
One-third of all older people live alone. Being with people daily has a positive effect on morale, well-being and eating.

Multiple Medicines
Many older Americans must take medicines for health problems. Almost half of older Americans take multiple medicines daily. Growing old many change the way we respond to drugs. The more medicines you take, the greater the chance for side effects such as increased or decreased appetite, change in taste, constipation, weakness, drowsiness, diarrhea, nausea, and others. Vitamins or minerals when taken in large doses act like drugs and use can cause harm. Alert your doctor to everything you take.

Involuntary Weight Loss/Gain
Losing or gaining a lot of weight when you are not trying to do so is an important warning sign that must not be ignored. Being overweight or underweight also increases your chance of poor health.

Needs Assistance in Self Care
Although most older people are able to eat, one of every five have trouble walking, shopping, buying and cooking food, especially as they get older.

Elder Years Above Age 80
Most older people lead full and productive lives. But as age increases, risk of frailty and health problems increase. Checking your nutritional health regularly makes good sense.

The Nutrition Screening Initiative
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Maryland State Board of Pharmacy

Title 10

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 34

BOARD OF PHARMACY
10.34.23 Pharmaceutical Services to Residents in Long Term Care Facilities

These regulations were adopted and are effective as of October 7, 1996.

Questions concerning these regulations should be directed to the Board of Pharmacy at (410) 764-4755.

.01 Scope.

These regulations apply to all pharmacies and pharmacists servicing facilities as defined in section .02 except for pharmacies only providing emergency services for these facilities and operating under a contract with a pharmacy which is in compliance with these regulations.

.02 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms defined.

(1) "Emergency drug kit" means a box containing medications which may be required for the emergency need of a resident and which may not be available from any other authorized source in a timely manner.

(2) "Interim Box" means a container holding small amounts of medications intended to expedite immediate initiation of dosing until the pharmacy is able to provide a regular supply. The drugs in this container are not necessarily for emergency use only.

(3) "Long term care facility", also referred to as "the facility" means any facility, other than an acute care facility, providing pharmaceutical services to residents or residents housed in the facility, including but not limited to the following:

(a) "Comprehensive care facilities" as defined in COMAR 10.07.03.01B(6);

(b) "Domiciliary care homes" as defined in COMAR 10.07.03.01D;

(c) "Extended care facilities" as defined in COMAR 10.07.02.01B(6);

(d) "Nursing facilities" as defined in COMAR 10.07.02.01B(25); and

(e) "Correctional facilities" , which means a place of incarceration maintained by a governmental agency where persons are confined after committing a criminal act or in violation of the law.

(4) "Long term care pharmacy", also referred to as "the pharmacy" means a pharmacy which has been issued a permit by the Board of Pharmacy and which provides pharmaceutical services to residents in a long term care facility.

(5) "Pharmaceutical care", also referred to as "Pharmaceutical services" means the care or services afforded by the licensed pharmacist or licensed pharmacy to the resident that is required by practice standards, laws, regulations, and guidelines.

(6) "Pharmacy area" means that portion of the licensed pharmacy where medication and other products requiring a prescription by Federal or State law are stored and where the prescriptions are compounded or prepared.

(7) "Verbal order" means an order that is orally communicated to a person authorized to accept a prescription order by someone who is authorized to communicate a prescription.

(8) "Written order" means an order that is directly written by an authorized prescriber, or a transcription of an order from an authorized prescriber.

.03 Licensing.

A. A pharmacy must have been issued a permit by the Board of Pharmacy before the pharmacy may operate in Maryland.

B. A pharmacist must have been issued a license by the Board of Pharmacy before the pharmacist may practice in Maryland.

.04 Policy and Procedures.

A. The pharmacy must operate under a written set of policies and procedures. Such policy and procedures shall define the scope and method of pharmacy services appropriate to the staff and to the residents served at the facility, and will reflect the policies and procedures of the facility serviced.

.05 Personnel.

A. Director of pharmacy.

(1) Each pharmacy shall be under the supervision of a pharmacist, hereinafter referred to as the director of pharmacy, who is licensed to engage in the practice of pharmacy in this State, and who is knowledgeable in, and thoroughly familiar with, the specialized functions of long term care pharmacies. The director shall be responsible for all activities of the pharmacy, and for meeting the requirements of the Health Occupations Title 12, Annotated Code of Maryland and this chapter.

B. The director of pharmacy shall be assisted by additional licensed pharmacists and ancillary personnel as may be required to operate such pharmacy to meet the needs of the residents of the facilities which it services)

(1) The policies and procedures shall specify that ancillary personnel are directly and personally supervised by a licensed pharmacist and that they are not assigned duties which may be performed only by licensed pharmacists.

(2) Secretarial and clerical assistance and support may be provided as required to assist with record keeping, report submission and any other administrative duties.

C. Supervision.

(1) All of the activities and operations of the pharmacy shall be under the direct supervision of the director or licensed pharmacist designee of the director.

.06 Physical Requirements.

A. Storage.

All medications and supplies within the pharmacy shall be properly stored with respect to sanitation, temperature, light, ventilation, moisture control, segregation, and security.

B. Equipment and Materials.

Each pharmacy shall have the appropriate professional and technical equipment, supplies and physical facilities for proper compounding, dispensing and preparation of medications, including parenteral preparations if applicable. It shall also have appropriate reference materials to enable personnel to prepare and dispense medications properly.

C. Security.

The director shall designate in writing, policies and procedures regarding the personnel who have access to the pharmacy area.

(1) No one shall be allowed in the pharmacy area unless a pharmacist is on duty.

(2) The pharmacy area shall be enclosed in such a manner as to prevent persons not authorized from entering it after being secured by the pharmacist.

(3) A suitable enclosure shall be deemed one which protects the prescription medication stock against unauthorized entry.

.07 Medication and Device Distribution, Control and Accountability.

A. General.

The procedures and policies of the pharmacy shall provide for the safe and efficient dispensing and delivery of pharmaceutical products. An annually reviewed copy of such procedures shall be on hand for inspection.

B. Responsibility.

The director or licensed pharmacist designated by the director shall be responsible for the safe and efficient dispensing, delivery, control of, and accountability for medications and certain devices. The director shall work in cooperation with the other professional staff of the facility in meeting this responsibility and in ordering, storing, and accounting for pharmaceutical materials. Accordingly the director or designee shall be responsible for, at a minimum:

(1) Preparation under aseptic conditions of parenteral and other medications compounded in the pharmacy as applicable;

(2) The proper preparation, storage and distribution of parenteral admixtures to the extent that the functions are performed at the pharmacy;

(3) The prepackaging and pre-labeling of medications;

(4) The repackaging of medications at the pharmacy;

(5) Records of all transactions of the pharmacy as may be required by applicable law and as may be necessary to maintain accurate control over and accountability for all pharmaceuticals, including current resident medication profiles;

(6) Participation in those aspects of the

facility's quality assurance improvement program which relate to pharmaceutical care and effectiveness; and

(7) Implementation of the policies and decisions of the appropriate committee(s) of the facility related to these regulations and to other regulations of the facility.

C. Prepackaging and Repackaging.

(1) The manual or automated selection of prepackaged and pre-labeled doses of medication and the repackaging of medication in unit dose packages or any other form of repackaging must be performed by or checked by a pharmacist for:

(a) Accuracy;
(b) Completeness; and
(c) Appropriateness;

(2) Proper labeling of the medication container must include:

(a) The brand or generic name of the medication;

(b) The strength of the medication if appropriate;

(c) The name of the distributor or manufacturer and the lot number; and

(d) The expiration date which shall be the lesser of 12 months from the date of repackaging; the manufacturer or distributor's listed expiration date; or the maximum time period allowed for the specific packaging used for the medication unless the pharmacist has reason to reduce the time period.

(3) The pharmacy may use a lot number and expiration date assigned by the pharmacy in lieu of the distributor information provided that a master log is kept with respect to all drugs that are repackaged within the facility which includes the:

(1) Name of drug,
(2) Strength of the drug,
(3) Manufacturer of the drug,
(4) Lot number assigned by the pharmacy,
(5) Quantity repackaged,
(6) Expiration date as described in .07C (2)
(7) Manufacturer's expiration date,
(8) Lot number assigned by the manufacturer,
(9) Date of repackaging,
(10) Name of repackager, and
(11) Name of verifying pharmacist

D. Labeling.

(1) All medications dispensed by the pharmacy, intended for use within the facility, shall be dispensed in appropriate containers and shall be labeled with the:

(a) Name and address of the pharmacy;
(b) Date of dispensing
(c) Prescription number assigned by the pharmacy;
(d) Name of resident on the container;
(e) Name, quantity, and strength of the drug;
(f) Name of the prescriber;
(g) Expiration date of the drug when required by law;
(h) Required precautionary information regarding controlled substances; and,
(I) Such other and further cautionary information as may be required or desirable for proper use of the medication.

(2) When medication is provided per dosing period in a single container, slot, blister package or any other method of delivering an entire single dosing unit, labeling requirements may be met through the use of methods established as Policy and Procedures of the facility. These methods must be such that the medication is delivered in a way intended to ensure that the patient will receive the proper medication and that all other information identified in D (1) to (F) is provided either on the individual doses or some other means to insure availability.

(3) Medications in Parenteral Admixtures.

(a) Whenever any medication is added to a parenteral admixture by the pharmacist or by an appropriate person under the pharmacist's supervision such admixture shall be labeled with a distinctive supplementary label indicating the:

(I) Name of the drug and the amount of the drug added;
(ii) Expiration date; and
(iii) Identification of the pharmacist responsible for the preparation of the admixture.

E. Discontinued medications.

(1) The director will develop a means for the pharmacy to be notified of medications which have been discontinued.

(2) Only sealed, unopened packages or individual unit dose blisters may be returned to the inventory of the pharmacy.

(3) Medication classified as Schedule II,

Schedule III, Schedule IV, and Schedule V may not be returned to the inventory of the pharmacy.

(4) Medication requiring refrigeration may not be returned to the inventory of the pharmacy.

F. Emergency Drug Kit Or Electronic Equivalent.

(1) Emergency drug kits or electronic equivalent shall be secured with a tamper evident seal or electronic security system which will indicate the opening of the kit.

(2) Labeling.

(a) The exterior of the emergency kits shall be labeled so as to clearly and unmistakably indicate that it is an emergency kit for use in emergencies only.

(b) A listing of all medications contained within the kit shall be visible without opening the kit and secured to the kit and shall indicate for each medication in the kit the:

(I) Name of the drug;
(ii) Strength of the drug;
(iii) Expiration date of the drug.

(c) All medications contained in the emergency kit shall be labeled with :

(I) Name of the drug;
(ii) Strength of the drug;
(iii) Expiration date of the drug;
(iv) Lot number of the drug; and
(v) Any other information required by the medical staff.

(3) Replacement of medications.

The pharmacy shall develop a means to be notified of the need to replace medications which have been used in emergency situations in the facility or which are expired, and shall make that replacement within 72 hours of notification.

G. Interim Box

An interim box may be provided by the pharmacy and kept at the facility if facility policy and procedures address an interim box and the pharmacy complies with these policies.

H. Prescriber Orders.

(1) Medications may be dispensed from the pharmacy only upon receipt of valid written or verbal orders of an authorized prescriber.

(a) A written order may be received by the pharmacy by facsimile or electronic transmission or by direct copy.

(b) A verbal order must be documented by the pharmacist in writing and a written order must be received by the pharmacy to verify the order.

I. Controlled Dangerous Substances.

(1) Accountability.

The pharmacy shall abide by all laws and regulations as defined in Health General Article, Title 27, Annotated Code of Maryland and COMAR 10.19.03.

(2) Storage and Security.

(a) The pharmacy shall establish effective procedures for storage and security of Schedule II CDS medications including limitation of access in the pharmacy to pharmacists.

J. Recalls.

The director shall develop and implement a recall procedure that can be readily activated to assure that all medications included in the recall are properly disposed of.

K. Adverse Medication Reactions.

(1) Significant adverse medication reactions shall be reported to the attending prescriber or designee and other parties as per the facility's policy and procedure manual.

(2) An appropriate entry on the resident's record shall be made when an adverse reaction is reported.

(3) The Director or pharmacist designee shall participate on the appropriate committee to establish procedures to ensure the aforementioned is accomplished.

L. Records and Reports

The director shall maintain such records and reports as may be required by law, this chapter, and the policies of the facility.

.08 Quality Management.

The director shall be responsible for developing procedures for an ongoing quality management program that includes a mechanism for reviewing and evaluating pharmaceutical services as defined in these regulations.

The Changing Role of Wholesalers in the Pharmacy Marketplace

Larry L. Braden, R.Ph.
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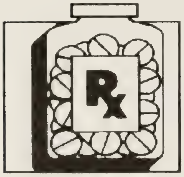

A number of economic forces that have come together over the past several months are reshaping the community pharmacy marketplace. Some of the forces began to emerge years ago when chain management, facing increased competition from growing discounter and grocery-pharmacy operations, began accepting ever-lower reimbursement rates from third parties. The resulting downward spiral of profitability has sucked chains and independents alike into the vortex. With their greater resources and strong management teams a number of chains have grown by increasing their market share while other chains, like many of their independent counterparts, have been absorbed into the chain consolidations. (The impact of the passage of "health care reform legislation" in late July remains to be seen. More about that later, but Medical Savings Accounts could alter the third-party marketplace).

America's wholesale drug industry is a world-class model of efficiency and cost-effective operations. The programs and services developed by wholesalers over the past two decades have allowed innovative and determined pharmacists to open new independent locations and have contributed greatly to the continued operations and success of the nation's twenty-five thousand independents. The relationship between wholesalers and chains, hospitals and other institutional purchasers of drugs has remained essentially unchanged over the past four decades. Wholesalers acquire products from manufacturers, warehouse the products, and ship in smaller quantities with greater frequency to end-distribution outlets. That's the basic pattern of any manufacturer/wholesaler/end-point distributor relationship. A few wholesalers have specialized in the chain- institutional markets. They carry a limited line of goods, primarily legend drugs, work on high turnover, extended dating from suppliers, and low margins.

Independent pharmacies are the core of the customer base for the majority of wholesalers and all of the larger ones. The independent/wholesaler relationship is mutually dependent and has been mutually beneficial. The beneficial aspect has led to a wide range of programs being developed by wholesalers to strengthen independents and to provide them with increased profitability. The dependent aspect, however, is troubling wholesalers because as their independent customers are consolidated into chain locations, driven by discriminatory pricing and third-party programs, wholesalers find their markets dwindling. They are responding with new programs they hope will help keep their independent customers in business and ostensibly will bring greater management assistance and new sources of revenue to those customers. On the surface these initiatives are giving independents the opportunity to participate in chain-like programs and have the potential to advance the concepts of pharmacy care. But questions should be raised by responsible voices about what the pharmacy market will be like in a few years if

> "On the surface these initiatives are giving independents the opportunity to participate in chain-like programs and have the potential to advance the concepts of pharmacy car. But questions should be raised by responsible voices about what the pharmacy market will be like in a few years if many of the roles of wholesalers and retailers are reversed."

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The wholesale industry has certainly not been immune to consolidations. Many independent wholesalers have joined ranks with the relatively new consolidating players in the market like AmeriSource and Cardinal. Last year's purchase of the Medicine Shoppe franchiser by Cardinal was the first direct entry of significance into the retail marketplace. Rumors abound that other wholesalers may follow that path. Bergen has announced a component of a program whereby the wholesaler will purchase the inventory of/for retail pharmacies and Cardinal has purchased the inventory of financially troubled K-Mart. McKesson has launched its national Caremax initiative and virtually all of the large wholesalers are rushing to jump on the disease management/ network bandwagon.

So what does this mean for independents and the pharmacy community? Much of the asset growth of wholesalers over the past several years can be attributed to inflation. Each time a manufacturer raises prices on goods held by the wholesaler, inventory values rise, assets rise, and net value increases. Inflation is an insidious force in our economy but it has dramatically enhanced the book value of wholesalers and retailers alike. In the new inverted marketplace apparently envisioned by many in the wholesale industry, rising asset values will accrue solely to them,. And if a retail pharmacy essentially becomes an outlet for the goods and services of the wholesaler, who influences the destiny of whom? Will a pharmacy realistically be able to tell wholesaler A to come pick up all of its inventory if the pharmacist thinks it more prudent to develop a new relationship with wholesaler B? One can envision scenarios in which pharmacists *own* an inventory of gifts and sundries and serve as a *distributor* for everything else owned by the wholesaler. On the other hand, many successful retailers have built their businesses based upon consignment inventories.

One parallel can be found in, of all places, chicken farmers. Not too many years ago in the Southeast local farmers borrowed money, built chicken houses, bought chicks, bought feed, and sold chickens in the open marketplace. As the years went by agricultural conglomerates, i.e. wholesalers, said, "Well take much of that work and worry about money off your hands, Mr. Farmer." Now a class-action suit has been filed against one of the largest conglomerates claiming that the farmers, who now own nothing but the hen houses, are being charged ever-rising prices for feed and are being paid ever-lower prices for chickens. The independent pharmacy community needs to clearly understand the economic and legal consequences of these new initiatives. Ownership of assets is capital; capital provides leverage; leverage forms the basis for the use of credit and credit allows for business expansion and growth.

Larry Braden has been the Executive Vice President of the Georgia Pharmacy Association since 1978. As Executive Vice President, Mr. Braden is responsible for overseeing the several non-profit and for-profit companies within the GPhA structure. Other organizations within the GPhA corporate structure include The Insurance Trust, Georgia Pharmaceutical Services, Inc., Pharmacy Providers of Georgia /the Pharmacy Advantage System, and the Georgia Pharmacy Foundation and its Prior Approval Unit. The operational budget of the association and its subsidiaries is over $ 6 million annually.

Mr. Braden is also principal owner Lacey Drug Company, Inc., three independent pharmacies located in Acworth, Georgia and Marietta, Georgia.

A Pharmacy Christmas Carol

Mary Chaffee, R.Ph.
Springs Drug Store, Burton, Michigan

Once upon a time, on the eve of Pharmacy Week, Old Ed Scrooge sat busily in his office while counting the daily receipts of Scrooge Pharmacy and keeping an eye on his intern, Rob Cratchit. Although the fall's chill was coming in, Ed still hadn't turned on the furnace.

"Happy Pharmacy Week, Uncle," cried a cherry voice. It was the voice of Scrooge's nephew, who entered so quickly that this was the first indication of his approach. "Bah," said Scrooge. "Humbug."

"Surely you don't mean that!" said the nephew. "What is Pharmacy Week?" asked Scrooge. "A time to pay your MPhA dues; a time for watching your gross margin fall while seeing another ridiculous insurance contract come in the mail?"

"Come to the BMPA CE program tomorrow night." pleaded the nephew. "Perhaps your old friends can cheer you up."

"Bah, humbug! Be gone with you!" bellowed Scrooge in return.

Well after nine o'clock, when the customers had long since departed, Rob Cratchit was putting on his coat to leave.

"You'll want tomorrow night off for that banquet, I suppose?" Asked Scrooge. "If it's convenient, sir."

"It's not convenient," replied Scrooge. "But I suppose I have no choice. Be here all the earlier tomorrow morning."

The overworked intern promised he would, and Scrooge walked out with a growl. He shuffled home as the fog and darkness thickened around him and the cold became intense. Scrooge ate his Budget Gourmet dinner at home in solitude while looking over his ledgers, then retired to his gloomy bedroom. Having heard strange noises below, Scrooge closed his door and locked himself securely in the house. Being satisfied with that, he put on his PJ's and went to bed.

Suddenly, a clanking noise rang deep down below, as if some person were dragging a heavy chain up the basement stairs. The basement door flew open with a bang, and Scrooge heard the noise much more loudly, coming up the next set of stairs towards his door. Through his bedroom door came the apparition, and Scrooge could see that it was the ghost of his business partner, Bob Marley. Marley's body was transparent and had a long chain wrapped around his waist.

"Why do you walk the earth and come to trouble me?" Scrooge implored.

"How is it that I appear before you in a shape that you may see, I may not tell, however, I come to warn you. You will be haunted by three spirits. Expect the first one when the bell tolls one." With that, the apparition drifted backwards and faded away.

Old Ed Scrooge went down to examine the locked door, only to find it undisturbed. "Humbug," he said and went back to bed to fall instantly asleep.

As foretold by Bob Marley's ghost, when the clock struck one, a strange figure appeared at the foot of Scrooge's bed. "Who and what are you?" Scrooge demanded.

"I am the Ghost of Pharmacy Past."

"Long past?"

"No, your past." The apparition put out its strong hand as it spoke and clasped him gently by the arm. "Rise and walk with me."

With that, the ghost and Scrooge passed through the bedroom wall and stood in an old pharmacy, complete with a soda fountain.

"Good heavens!" said Scrooge, clasping his hands together as he looked about him. "This is where I started out in the profession!"

Across the store was the young intern Scrooge in a starched white jacket, engaged in conversation with an elderly woman. Young Scrooge was explaining how her new heart medication made her heart beat stronger. She thanked him profusely, patted his hand and made her way out into the crisp fall afternoon. A young woman entered with her crying infant and Scrooge poured her a potion to relieve its colic.

Why did he rejoice to see these sights? Why was ol' Scrooge's heart warming to see these things that had been?

In bounded two of his classmates engaged in cheerful banter Old Scrooge turned to the ghost and said excitedly, "There's Dewayne Robinson and Al Kent, to be sure!" "Yo ho, there Eddie!" Al said to young Scrooge. We've come to give you a ride to the MPhA CE meeting."

"Ready whenever you are, Big Al!" young Scrooge replied. "I hear there's a great speaker tonight." With that, off they strode, looking like The Three Musketeers.

"I have seen your nobler aspirations fall off one by one, until the master passion, Gain, engrosses you, have I not?" inquired the ghost. Scrooge retorted angrily,

"What then? Even if I have grown so much wiser, what then? Take me back. Haunt me no longer!"

Scrooge then became conscious of being exhausted and overcome by irresistible drowsiness, then of being alone in his bedroom. He sank into a heavy sleep.

Awakening mid-snore, Scrooge heard the bell toll and woke as the second messenger arrived, sent to him at Bob Marley's intervention. He pulled back the blankets to find that his bed chamber had undergone a surprising transformation. In place of wall and ceiling hung so much greenery and apple trees that it looked like an orchard. Brightly hued fall leaves were scattered amongst the trees and heaped upon the floor were bushels of apples and neat rows of pumpkins.

"Come in!" commanded the ghost. "I am the Ghost of Pharmacy Present. Look upon me."

Scrooge reverently did so. The ghost was clothed in a flowing burnt-orange robe bordered with rabbit fur. Its dark brown curls were long and free, and its sparking eyes and cherry voice gave it a joyful air.

"Touch my robe." Scrooge did as he was told and held the robe fast.

Both he and the ghost were instantly transported to a bustling Rite Aid Pharmacy. Several pharmacists were busy at computer screens transcribing prescriptions which were appearing on the screens.

"Where are those prescriptions coming from?" demanded Scrooge.

"Twelve hundred doctors' offices are computer linked to Rite Aid Pharmacies," the ghost answered.

"Surely this is in the future, not the present, Spirit."

"Oh, but you are wrong, my good man. It is astounding where modern technology has taken us in a short time. I could show you much more of this, but our time is running short. Now let me show you where you are today, Mr. Scrooge."

With that, Scrooge and the Ghost of Pharmacy Present were whisked back to familiar Scrooge Pharmacy. Ed Scrooge was there at his computer grumbling over his rebillings, too busy to properly counsel his patients.

"I give them the information sheet that the computer generates now," Scrooge offered as an explanation.

"Do you think little Jason Flanders knows how to properly use his inhaler? And did you know that Gladys O'Malley can't read? How is she going to know that she shouldn't take her Maalox with the Cipro prescription you just dispensed for her?"

Scrooge's head hung down in shame at his comment.

From the folds of its robe, the ghost brought forth a small boy. Wretched, frightful and miserable, the boy knelt down at the ghost's feet and clung to the outside of the garment.

Scrooge started back, appalled. "Spirit, is he yours?"

He is all pharmacists, " said the spirit, looking down upon him. "This boy is Ignorance. Beware of him and all his kind. On his brow I see written Doom, unless the writing is erased."

Scrooge then looked about him for the ghost and saw it not. He was again quite alone in his gloomy bed chamber. A throbbing headache came upon him, so he took some Tylenol PM and laid back down.

When the bell tolled three, another phantom gravely, silently approached Scrooge. Shrouded in a deep black garment, is was completely concealed in the cloth, except for one outstretched hand.

"Are you the Ghost of Pharmacy yet to come?" inquired a groggy Scrooge. The spirit did not answer, but pointed onward with its outstretched hand.

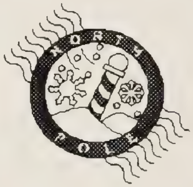
"Ghost of the Future," he exclaimed. "I know your purpose is to do me good, and I hope to be a different man from what I was. Will you not at least speak to me?" The ghost gave no reply. The hand pointed straight before them. "Lead on," said Scrooge. "Lead on."

Suddenly, Scrooge and the Ghost of Pharmacy Future were in the center of a small town. Groups of people were scattered along the sidewalk, engaged in conversation.

The spirit stopped beside a pair of elderly women standing in front of a gigantic vending machine. Observing that the hand was pointed to them, Scrooge advanced to listen to them talk.

"This is so convenient," said a portly woman in a pink dress as she stuffed a plastic card into the gleaming machine. She punched in a number as she continued, "I can come at any time of the day or night and get my prescription filled. Besides, the pharmacist never really talked to me about my prescription anyway. I wonder whatever happened to him?"

As she spoke, a bag containing her prescription popped out into the plastic bin at the bottom. On in was attached an information sheet and her receipt.



"I 'm not sure," replied the other woman. "I think Ed is working for Medco, the company that services the APM machines."

"Spirit!" Scrooge said. "This is a horrible scene. This lesson is not lost on me. Please take me back!"

The phantom spread its dark robe like a wing, withdrew it, and revealed a brightly lit conference room in a large hospital.

"I'm afraid the news is bad," the director began nervously. "The administration has forced us to lay off many of our pharmacist. Since Medco is supplying the premixed IV bags and most of you refused to go on clinical rotation, we need only a few pharmacists to check carts and do STAT orders. I tried to go to bat for you, but since most of your work could be done by technicians, the administration didn't feel it could justify the cost of your positions."

There amongst the group was a middle-aged Rob Cratchit, with his jaw slack and color draining from his face.

"Spirit, are these shadows of things that will be, or are they shadows of things that may be only?" The ghost was immovable as ever. "Spirit!" he cried, clutching tight at its robe, "Hear me! I am not the man I was. Assure me that I may change. Let me prove that these shadows you have shown me can be altered!"

"I will honor pharmacy in my heart and keep it all the year. I will remember that is a noble profession, not just a job. I will provide pharmaceutical care and document it, starting now! I won't wait for reimbursement, I will make the commitment now. Please tell me that it's not too late!"

Holding his hands in a last prayer to have his fate revised, he saw an alteration in the phantom's robe, which shrunk, collapsed and dwindled down to a bedpost.

Yes! The bedpost was his own. The bed and room were his own, too. Best of all, the time was his own to make amends in!

Scrooge bounded down the stairs, busily clothing himself, giddy as schoolboy. He went dancing down the street to his pharmacy and regarded everyone with a delighted smile.

Rob Cratchit, Scrooge's intern, was waiting by the back of the store. "Mr. Scrooge?"

"Good day, my dear intern, and happy Pharmacy Week to you!" Scrooge replied. "I think we should start this day with a raise in salary, don't you think?" Rob Cratchit stuttered in shock, "I - I . . ."

"Well, of course. You worked so hard this summer for me. And how about that consultation room you've been trying to create? It's about time for that, too. I think I'll call the MPhA and see if it's not too late to sign up for the next CE program. We need to get caught up to the 1990's. Say, were there any tickets left for the BMPA dinner?" Cratchit was dumbfounded.

Ed Scrooge was better than his word. He made the changes and even more. He served his profession well with thorough patient consultations and participated on MPhA committees when asked. Some people laughed to see the changes in him, but he heeded them little because he knew that nothing ever happened for good as which some people did not have their fill of laughter. In truth, his own heart laughed, too, and that was good enough for him.

He had no further visitations from the spirits, but never forgot his lessons from them. From that day on, it was always said of him that he knew how to keep pharmacy well, if any man possessed the knowledge. Whether we be from hospital, retail, employee or manager, may the same be truly said of us all.

"A Pharmacy Carol" was revised and reprinted with permission from the Michigan Pharmacists Association. Mary Chaffee, a pharmacist at Spring Drug Store in Burton, Michigan, serves as a member of the Board of Trustees of the Michigan Society of Community Pharmacists.

Happy Holidays

NEW DRUGS IN BRIEF . . .*

Trade Name: Xalatan

Generic Name: Latanoprost

Dosage Forms: 0.005% Ophthalmic Solution

Therapeutic Category: Agent for Glaucoma

Mechanism of Action: Is a prostanoid selective FP receptor agonist which is believed to reduce the intraocular pressure by increasing the outflow of aqueous humor. Studies suggest that the main mechanism of action is increased uveoscleral outflow.

Indications: For the reduction of elevated intraocular pressure in patients with open-angle glaucoma and ocular hypertension who are intolerant of other intraocular pressure lowering medications or insufficiently responsive to another intraocular pressure lowering medication.

Pre-dispensing Notes: Iris pigmentation changes occur in affected eye due to an increase in brown pigment. In clinical trials, no statistically significant effects on heart rate; no statistically significant effect on systolic or diastolic blood pressure. In asthmatic patients without glaucoma, had no negative effects on respiratory function.

Drug Interactions: Precipitation occurs when eye drops containing thimerosal are mixed with Xalatan. Administration of such drugs should be administered at a minimum of a five minute interval.

Therapeutic Advantage: Once daily dosing.

Trade Name: Accolate

Generic Name: Zafirlukast

Dosage Forms: 20mg oral tablets

Therapeutic Category: Leukotriene Receptor Agonist - Prevents Bronchoconstriction

Mechanism of Action: Is a selective and competitive receptor antagonist of leukotriene D_4 and E_4, (components of slow-reacting substance of anaphylaxis), resulting in a reduction of bronchoconstriction.

Indications: For the prophylaxis and chronic treatment of asthma in adults and children 12 years of age and older.

Pre-dispensing Notes: Not a bronchodilator and should not be used to treat acute episodes of asthma. Other asthma medications should not be stopped or decreased upon initiation unless the patient is instructed to do so by the prescriber. Nursing mothers should not take zafirlukast. Decreased clearance has been noted in the elderly.

Drug Interactions: Co-administration with warfarin results in clinically significant increases in prothrombin times. Times should be monitored and adjusted accordingly.

Dosage and Administration: 20mg twice daily at least one hour before or 2 hours after meals.

* INFORMATION CONTAINED IN NEW DRUGS IN BRIEF IS FOR EDUCATIONAL PURPOSES ONLY AND SHOULD NOT BE CONSIDERED ALL-INCLUSIVE. MPHA IS NOT RESPONSIBLE FOR RELIANCE ON THIS INFORMATION. ALWAYS READ MANUFACTURER LITERATURE PRIOR TO DISPENSING.

Trade Name: Viramune

Generic Name: Nevirapine

Dosage Form: 200mg oral tablets

Therapeutic Category: Non-nucleoside Reverse Transcriptase Inhibitor

Mechanism of Action: Bonds directly to reverse transcriptase (RT) and blocks the RNA-dependent and DNA-dependent DNA polymerase activities of HIV-1 by causing a disruption of the enzyme's catalytic site. The activity does not compete with template or nucleoside triphosphates. HIV-2 RT and eukaryotic DNA polymerases are not inhibited.

Pre-dispensing Notes: Therapy must be initiated with a 14 day lead in period of 200mg/day to reduce the occurrence of rash. Dose escalation should not occur until any rash observed during lead-in period is resolved.

Precautions: Rash, which occurs in approximately 20% of all patients, may be sever or life-threatening. Occurrence of moderate or severe abnormal liver function tests, including cases of hepatitis, is cause for discontinuation of drug until liver function returns to normal. Recurrence of moderate or severe liver function abnormalities upon re-initiation of therapy is cause for permanent discontinuation of therapy.

Drug Interactions: Dosage adjustments may be necessary with co-administration of Rifampin and Rifabutin; therefore, when use in combination is necessary, close monitoring is required. Concentrations of protease inhibitors and oral contraceptives may be decreased with nevirapine, and should not be administered concomitantly until further research is done.

Dosage: Initial dose is 200mg daily for 14 days, with an increase to 200mg twice daily in combination with nucleoside analogue antiretroviral agents.

BMPA News

The Baltimore Metropolitan Pharmacists Association is pleased to report that Dnniel Satisky, P.D., outgoing President of the Association, was selected to receive the Merck Pharmacist Award. The award recognizes professional and civic achievements of pharmacists. The award was presented by Frank Radigan, Disctrict Manager, Merck & Co.

Jean Freels, P.D. accepted her appointment as 1996-97 President of the Baltimore Metropolitan Pharmacists Association at the BMPA Annual Continuing Education/Dinner Meeting on October 23, 1996.
Dr. Freels has served on the Executive Committee of BMPA since 1991, and is the President - Elect of the Maryland Pharmacists Association.

All officers of the Baltimore Metropolitan Pharmacists Association will be installed at the Association meeting scheduled for December 3, 1996.

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I certify that the above statements made by me above are correct and complete
Tracy L. Baroni, R.Ph., J.D. September 25, 1996

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Continuing Education for Pharmacists

Patient Counseling: Self-Treatment of Heartburn, Part 2: The Products

Thomas A. Gossel, R.Ph., Ph.D., Dean, and Professor of Pharmacology and Toxicology, Ohio Northern University, Ada Ohio

and

J. Richard Wuest, R.Ph., Pharm.D., Professor of Pharmacy Practice, University of Cincinnati, Cincinnati, Ohio

A professional development program made possible by an educational grant from

SEARLE

Goals

The goals of this lesson are to discuss the treatment of heartburn, sour stomach and acid indigestion with OTC products, and to present information to use when counseling patients. Throughout this lesson, these symptoms will be referred to collectively as *heartburn*.

Objectives

At the conclusion of this lesson, successful participants should be able to:

1. identify OTC drug product ingredients that are used to treat heartburn;
2. choose from a list the major pharmacologic and toxicologic properties of the drugs;
3. identify interactions associated with the drugs, and state their extent of chemical significance;
4. differentiate between the therapeutic applications of OTC drug products used to treat heartburn; and,
5. demonstrate the ability to counsel patients on the treatment of heartburn with OTC products.

Antacids

Effective and inexpensive for treating heartburn, antacids are reportedly consumed chronically by approximately 85 percent of patients who have heartburn. More than $500 million each year is spent on antacids in the U. S. This places them among the most popular of all OTC products. Antacids are purchased largely in pharmacies, and comprise a major product category for which consumers seek pharmacists' advice before purchasing.

Antacids promote relief of symptoms by neutralizing the free hydrogen ion concentration of gastric juices so that, if reflux occurs, the esophageal lining can resist its corrosive action and irritation will be minimized. Antacids neutralize only the existing acid. They have no effect on the quantity of gastric acid secreted or its rate of secretion. The amount of acid that is neutralized is dependent on the dose and type of antacid preparation. Increasing the gastric pH from 1.3 to 2.3 effectively neutralizes 90 percent of acid. Increasing the pH to 3.3 neutralizes approximately 99 percent of acid. By increasing the gastric pH, antacids also inhibit formation of pepsin from pepsinogen since this conversion is a pH-dependent process. Pepsin, in combination with hydrochloric acid, forms the corrosive gastric juices.

Many antacid products contain salts of aluminum, calcium or magnesium, while most contain a mixture of aluminum and magnesium. This combination maximizes the neutralizing capacity, while minimizing the laxative effect of magnesium ions, and constipative property of aluminum ions.

Sodium bicarbonate can be used occasionally for acute treatment of heartburn. It is not suitable for treatment of symptoms of GERD because it releases carbon dioxide which can increase the intraabdominal pressure and worsen the condition.

The solubility of an antacid determines its onset of action: the more soluble, the more rapid its onset of action. Both sodium bicarbonate and magnesium hydroxide dissolve quickly at the acidic gastric pH and have a rapid effect. Aluminum hydroxide and calcium carbonate, on the other hand, dissolve slowly and require as long as 30 minutes to work. Liquid formulations dissolve more quickly than tablets. Chewing antacid tablets well before swallowing enhances dissolution and ensures maximum therapeutic benefit. Thorough chewing also avoids the lodging of undissolved tablets in the esophagus.

The neutralizing action of antacid products differs according to the length of time they remain in the stomach. Since the presence of food slows gastric emptying, antacids taken on a full stomach normally have a longer duration of action, up to 3 hours, compared to those taken on an empty stomach, approximately 30 minutes. Magnesium hydroxide and sodium bicarbonate have the shortest duration of neutralizing action. Aluminum hydroxide and calcium carbonate have the longest duration of neutralizing action.

The optimal dose for most patients is not known and probably varies among individuals. The lowest dose suggested on the label should be used initially.

Products containing calcium should not be used over a prolonged period since they can cause acid rebound. All antacids should be used cautiously in persons with renal disease.

Many orally-administered drugs may interact with antacids to increase or decrease the drugs' action. While the significance of many of these interactions is questionable, FDA has proposed that the labeling of OTC antacids be changed from warning about a potential interaction with tetracycline derivatives-only, to a drug interaction precaution statement warning that antacids can interact with all prescription drugs. Patients should be advised to not self-medicate with antacids concurrently with any prescription drug. This does not mean they are contra-indicated. Rather, it means that before deciding whether to take an antacid, persons taking prescription drugs should seek the advice of a health care practitioner. In most instances, allowing two hours to elapse between doses of the other drug and the antacid will avoid the problem.

The most significant interactions are those with antacids containing aluminum, calcium, or magnesium, and drugs that can be chelated (bound) to them. The result is reduced absorption, thus decreasing pharmacologic activity. Certain quinolone antibiotics, tetracycline derivatives, and iron preparations are affected particularly.

For maximum relief of symptoms, antacids should be taken approximately 30 minutes after meals. Chewable tablets should be chewed thoroughly before swallowing and followed with a full glass of water to allow sufficient wetting of the antacid. Effervescent tablets should be allowed to dissolve completely and the bubbles to dissipate before consuming the dose.

Alginic Acid

A combination of alginic acid plus antacid is used to treat heartburn. The quantity of antacid in the combination is insufficient to alter the intragastric pH. The antacid functions to convert alginic acid to sodium alginate.

Sodium alginate does not mix with the gastric contents. Rather, it forms a viscous gel layer, termed a *raft of foam*, that floats on the surface of the gastric contents. Concurrently, bicarbonate reacts with gastric acid to form carbon dioxide gas. The alginic acid entraps these gas molecules to form the raft that floats to the surface. If reflux should occur, the nonirritating foam, rather than irritating gastric contents, bathes the esophageal lining. This foam barrier may also physically block reflux of gastric contents into the esophagus.

To illustrate this, 10 patients with mild to moderate symptoms of heartburn were

Table 1

H_2-Blocker Products for Self-Treatment of Heartburn, Sour Stomach and Acid Indigestion[1]

GenericName	**Trade Name**	**Indication(s)**	**Dose**
Cimetidine	Tagamet HB[2] (100mg tablets)	Relief of heartburn, acid indigestion and sour stomach	Two tablets with water as symptoms occur or as directed. Maximum dose: 4 tablets in 24 hours.
Famotidine	Pepcid AC[2] (10mg tablets)	Relief of heartburn, acid indigestion and sour stomach	One tablet with water as symptoms occur or as directed.
		Prevention of these symptoms brought on by consuming food and beverages	One tablet one hour before eating a meal expected to cause symptoms. Maximum dose: 2 tablets in 24 hours.

1. At the time of preparation of this lesson, OTC versions of Zantac and Axid had been approved for switch to OTC status, but were yet unmarketed.
2. HB = Heartburn; AC = Acid Controller

entered in a study to compare traditional antacid therapy with an alginic acid/antacid product. Each person received a symptom-provoking meal consisting of an egg-sausage biscuit containing 61 percent fat. Treatment was randomized to traditional antacid or the alginic/antacid combination product given immediately after the meal, and at one, two, and three hours afterward. The antacid had the same acid-neutralizing potency as the alginic acid/antacid combination. The alginic acid-containing treatment was significantly superior to traditional antacid in preventing the number of episodes and severity of reflux attacks.

Sodium alginate protects the esophagus by floating on the stomach contents only when patients are in an upright position. Consequently, alginic acid is effective when patients are sitting or standing, but is of little value when patients lie down.

Patients should be reminded to chew the alginic acid/antacid tablets well to ensure maximum effectiveness. They should also drink a full glass of water after the tablets have been chewed.

Low-dose H_2-receptor Antagonists

Two H_2-receptor antagonists (H_2 blockers) that were available formerly only on prescription are now marketed in low-dose formulations for self-treatment of heartburn, acid indigestion, and sour stomach. The drugs are cimetidine (Tagamet HB) and famotidine (Pepcid AC). They are profiled in Table 1. The other two H_2 blockers are approved for OTC status, but had not yet been marketed at the time of preparation of this lesson. Plans are to market ranitidine as Zantac 75, and nizatidine as Axid 75.

The prescription drug product Tagamet was the first H_2 blocker to be released and has been available since 1977. Pepcid has been marketed since 1985. Safety and efficacy for both drugs in prescription strengths have been well documented. Cimetidine has the distinction of being one of the most widely prescribed drugs of all times.

H_2 blockers are competitive inhibitors of histamine receptors on gastric parietal cells. Histamine is formed continually in the gastric mucosa. As it is released, it binds to H_2

receptors to block the triggering production of hydrochloric acid and increasing acid levels in the stomach. When H_2 blockers bind to the receptors to block histamine attachment, both daytime and nocturnal basal gastric acid secretion, as well as chemically-induced secretion, are reduced and the amount of hydrochloric acid in the stomach decreases. The resultant decreased volume of gastric juice reduces total pepsin production. While gastric reflux may continue to occur in patients who are taking the drugs, the effects of the reflux are much less irritating because the contents of the reflux are less acidic.

Cimetidine. Clinical experience with cimetidine has established an excellent safety record. Adverse drug reactions with oral cimetidine are uncommon. Those that do occur are minor. For example, adverse events that are reported most often are diarrhea and headache; both of these have been reported in only one to three percent of treated patients. An even lower incidence of adverse events is expected with the new 100mg dose.

Like antacids and some other H_2 blockers, cimetidine has the potential for interaction with other drugs. The primary interaction is altering their absorption or clearance. Potentially significant interactions are associated mainly with three drugs: phenytoin, theophylline, and warfarin. Cimetidine, but not at the 100mg dosage level, inhibits their metabolism, resulting in higher blood concentrations.

Famotidine. Unlike cimetidine, famotidine is indicated for prevention of symptoms brought on by consuming food and beverages. The benefit of Pepcid AC taken prophylactically may be the single most important application of the drug for patients who wish to self-treatment their symptoms.

An extensive safety profile has emerged with prescription-strength famotidine. This indicates that low-dose famotidine will be well tolerated. In clinical trials of Pepcid AC, the most common adverse effects reported were headache, dizziness, diarrhea, and nausea. Most adverse experiences were mild and transient. None occurred at the five percent or higher level.

To date, clinically significant drug interactions have not been noted with famotidine. Unlike cimetidine and ranitidine, famotidine does not modify the metabolism of compounds by affecting the hepatic cytochrome P-450 enzyme system.

Famotidine can be administered concomitantly (but not simultaneously) with antacids, if needed. A placebo-controlled study evaluated whether coadministration of a magnesium-aluminum hydroxide antacid would change the pharmacodynamics of famotidine 10mg or 20mg. The antacid failed to alter the effect of famotidine on intragastric pH.

No adequate and well-controlled studies in pregnant women have been performed. Therefore, Pepcid AC should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

The drug appears to be a safe in overdosage. There is no documented evidence of serious toxicity in patients who have taken more than 800mg of famotidine each day for hypersecretory conditions.

Counseling Patients on the Treatment of Heartburn With OTC Products

Most people probably attempt to self-treat heartburn before consulting a physician. Pharmacists, therefore, may be the first health-care provider to be consulted by patients with heartburn when they have specific questions. They can outline non-pharmacologic strategies for relief of heartburn and acid indigestion, recommend appropriate OTC therapy, and counsel patients on the proper use of the products.

Before recommending specific therapy, it must be determined whether the patient's complaint represents simple heartburn that is not associated with serious pathology, or whether the symptom(s) suggest a more serious underlying condition that requires professional evaluation and treatment by a

Table 2
Patient Counseling Tips for OTC Histamine-2 (H_2) Receptor Blockers

- Pepcid AC and Tagamet HB are used to relieve heartburn, acid indigestion, and sour stomach. Pepcid AC is also used to prevent these symptoms.
- To relieve symptoms, swallow one tablet with water. Do not chew.
- To prevent symptoms before they occur, swallow one Pepcid AC tablet one hour before eating a meal expected to cause symptoms.
- Do not take more than two tablets in 24 hours, or take the maximum daily dose for more than two consecutive weeks without checking with your doctor.
- Contact your doctor right away if persistent abdominal pain occurs. This may be a warning sign of a more serious condition that needs different treatment.
- This drug is not approved for use in pregnant women or children under the age of 12 unless directed by your doctor.

physician. Examples of potentially serious disorders that can mimic heartburn include benign or malignant pancreatic disease, coronary ischemia, gallstones, and peptic ulcer disease. OTC antacids, alginic acid/antacid combination, or H_2 blockers will not harm the individual in the absence of specific contraindications. The danger lies in the drug masking symptoms resulting in delay of treatment of a serious underlying pathology.

Likewise, patients should be advised to contact their doctor if heartburn is not resolved after two weeks of self-treatment. Failure to respond to OTC medication may indicate that they have a more serious condition.

Several factors should be considered when selecting an antacid, an alginic acid/antacid combination preparation or a low-dose H_2 blocker for treating occasional mild to moderate symptoms of heartburn in patients whose history does not suggest an underlying organic disorder. These include patient tolerability, the likelihood of compliance, and the use of concomitant medications.

Patients should be questioned about adverse effects experienced with medications used previously for the relief of their symptoms. To illustrate, patients who developed diarrhea while taking an antacid containing magnesium may be better treated with an antacid formulation containing aluminum hydroxide or calcium carbonate. A low-dose H_2 blocker may be even more appropriate. A long-acting agent, such as a low-dose H_2 blocker, may be more appropriate than a short-acting antacid for patients who find it difficult to remember to take medications.

Patients should be questioned about other medications being taken. They should be warned to avoid taking antacids within two hours of other drugs.

Patients should be evaluated by a physician if they have been unsuccessful in using nonpharmacologic methods for alleviating heartburn. These include avoiding foods, beverages and drugs that irritate the stomach wall, stimulate secretion of gastric acid, or lessen the tone of the lower esophageal sphincter.

Pharmacists can recommend alternate antacid products whenever patients develop a taste aversion to any product. They can also recommend a concentrated-dosage product if the size of the doses are inconvenient.

Patients may also find the consistency or the large volume of liquid needed to control their symptoms intolerable. Making patients aware of the concept of potency as measured by acid neutralizing capacity (i.e., the number of tablets or volume of liquid) is important. Helping them interpret the label of these products (i.e., sugar, sodium, and other contents) is also important. A review of a patient's other health problems and their prescription and non-prescription drug use will also help fine-tune the antacid choices.

Tips for counseling patients on OTC H_2 receptor blockers may be found in Table 2.

MPhA members can receive one contact hour of CE credit by completing and returning the CE quiz on page 38 of this issue. This program has been approved for one credit hour (0.1 CEU's) of ACPE approved continuing education. The Maryland Continuing Education Coordinating Council is an approved provider of continuing education programs for pharmacists by the American Council on Pharmaceutical Education.

ACPE # 144-999-96-017-HO1

Money Minute

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Why Growth Stocks Belong In Your Portfolio

Sure, you want your investments to grow. But after the summer's dip in the stock market, are you wondering about the wisdom of owning growth stocks?

Consider These Facts: You can't hide from inflation, so plan to outgrow it. For the long-term investor, inflation may present the greatest risk to your portfolio. Right now, inflation is low, but even a 4% annual rise cuts deeply into returns from "safe," fixed investments. Stocks offer the potential to appreciate at a faster rate than inflation, so your portfolio grows to offset eroding buying power.

Diversification can buffer risk and enhance returns. A portfolio that contains a mix of stocks, bonds, and other investments may have less overall risk because each reacts differently to changes in the economy. For example, Ibbotson Associates, Inc. has calculated that a 100% investment in the S&P 500 has a similar risk profile to a mix that includes 73% S&P stocks, 21% foreign stocks and 6% small-cap stocks. Yet the more diversified mix grew 12.9% a year over the past 25 years, compared to 12.2% for the pure blue chip stock portfolio.

Asset allocation -- establishing the right asset mix for you -- is a good way to keep growth in its proper place. The balance of growth stocks to other investments in your portfolio depends on your investment goals, time frame and risk tolerance. Once you determine a target mix of assets, you'll need to monitor it. Faster-growing stocks will push the mix out of balance, but selling some of the higher-performing assets and shifting assets to slower-growing categories will restore your portfolio to the desired mix. This maximizes your returns while keeping the risk level in line.

Add growth in a way that makes you comfortable. There are many ways to add growth stocks to your portfolio, including large and small-cap stock mutual funds or index funds. The key is making growth part of your overall investment strategy.

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Continuing Education Quiz

November / December 1996

This month`s questions are taken from the article on Patient Counseling: Self-Treatment of Heartburn, Part 2: The Products that appears in this issue. Circle your answers to the following questions and mail the entire page to Pharmacist Journal CE, 650 West Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members $ 5.00). The completed quiz for this issue must be received by December 31, 1997. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly. ACPE # 144-999-96-017-H01

Name ____

Address ____

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1. Antacids exert which of the following effects in alleviating heartburn?
    a. Affecting the quantity of acid secreted
    b. Directly binding with an inhibiting pepsin
    c. Neutralizing free hydrogen ion concentration
    d. Physically blocking access of hydrogen ions to esophageal tissue

2. The LEAST suitable antacid for treating symptoms of GERD is:
    a. aluminum hydroxide.
    b. calcium carbonate.
    c. magnesium hydroxide.
    d. sodium bicarbonate.

3. The reason that the antacid referred to in question 2 is LEAST appropriate for treating the symptoms of GERD is because it:
    a. causes constipation.
    b. can increase intraabdominal pressure.
    c. leads to hypercalcemia.
    d. increases laxation.

4. Histamine-2 blockers act primarily on gastric:
    a. chief cells.
    b. epithelial cells.
    c. parietal cells.
    d. gastrin-producing cells.

5. There are documented and potentially significant drug interactions between cimetidine and all of the following EXCEPT:
    a. antacids.
    b. phenytoin.
    c. theophylline.
    d. warfarin.

6. Drugs that increase stomach pH to reduce the corrosive effects of gastric juices inhibit the formation of:
    a. pepsin.
    b. gastrin.
    c. secretin.
    d. intrinsic factor.

7. H_2 blockers are approved for OTC sale for self-medication of all of the following symptoms EXCEPT:
    a. acid indigestion.
    b. sour stomach.
    c. heartburn.
    d. GERD

8. In most instances, two hours should elapse between doses of an antacid and:
    a. tetracycline only.
    b. tetracycline and its derivatives only.
    c. tetracycline and all other antibiotics only.
    d. any prescription drug.

9. The product(s) that has/have received approval for claims of effectiveness in both the relief and the prevention of symptoms brought on by consuming foods and beverages is:
    a. Pepcid AC only.
    b. Tagament HB only.
    c. Both Pepcid AC and Tagamet HB.
    d. Neither Pepcid AC nor Tagamet HB.

10. To obtain optimal neutralizing action, antacids are best taken approximately 30 minutes:
    a. before meals.
    b. after meals.

Classified Ads

Non-Profit Drug Education Caring Pharmacist Drug Education - A drug education and substance abuse detoxification referral service is launching a public relations campaign in the Baltimore City Schools for the 1996/1997 school year. If you would like participate in the program, please call Kemi Olunloyo, P.D., Public Relations Specialist at (410) 998-1033

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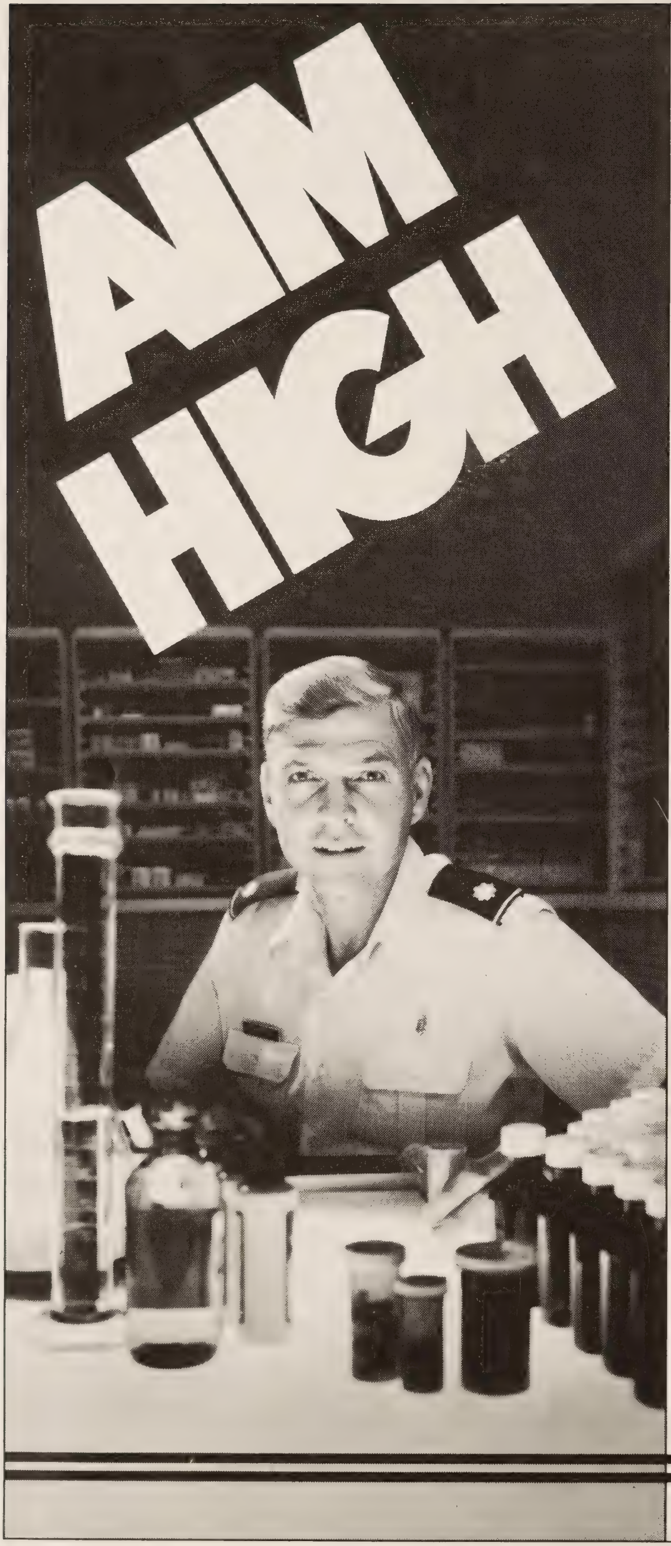
Call for APhA - Delegates - Maryland is entitled to 7 delegates at the 1997 APhA Convention, which will be held in Los Angeles from March 8 -12, 1997. In addition, we are permitted to appoint 5 alternate delegates. Each delegate must be an active member of APhA. Any interested person should contact the MPhA office at (410) 727-0746 or (800) 833-7587 for a Delegate Credential Certificate.

APhA/3M Pharmaceuticals Scholarship Program

Sixteen $500 scholarships, to be used for educational and professional development activities, will be awarded to one pharmacist and one pharmacy student in each of the eight APhA-ASP regions. Recipients will be an individual who: has demonstrated exceptional leadership and service to the profession of pharmacy through their coordination of and participation in patient education programs; is a full-time pharmacy student in good standing or is a licensed pharmacist; and is an APhA member. Contact the MPhA office at (410) 727-0746 or (800) 833-7587 for an application.



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President's Commentary

The 1997 MPhA Mid-Year Meeting

"Celebrate the Future of Pharmacy"

Sunday,
February 23
1997

MARYLAND PHARMACISTS ASSOCIATION

January / February 1997

Maryland Pharmacists Association
650 W. Lombard Street
Baltimore, MD 21201
(410) 727-0746

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President's Commentary

Delegation and More Delegation

Ernest Testerman, P.D., President

Our days are filled with confusion and too much to accomplish. There are questions to answer, patients to counsel, prescriptions to process, orders to check-in, and prescribers to telephone. What we need is a person to whom we can delegate some of these tasks. This person would be trained by the pharmacist (or a formal program) and be responsible to the pharmacist for the completion of certain tasks.

The delegation I have in mind is the delegation of tasks assigned to pharmacists from various outside sources. One of these sources is third party payors. Since most prescriptions are now paid by a third party we are required to follow the rules and formularies of the third parties. If the prescription is not on the formulary, we are obligated to call the prescriber for a therapeutic interchange. If the patient's insurance card is incorrect we must call the insurance company and correct it. TASKS, TASKS, TASKS.

Another source of delegation is the employer. Since an increasing number of pharmacists are employee pharmacists, we are delegated tasks by our employers. These tasks include ordering pharmaceuticals, preparing daily and weekly performance reports, processing returns, stocking vials, sweeping floors, and filling prescription orders. These tasks require a certain amount of time, technology, and personnel. Who assesses how much time, technology, and personnel are required? The employer.

A pharmacist must also be concerned when delegation occurs outside the walls of the pharmacy. Many prescribers delegate tasks to office personnel such as calling in and writing prescriptions. Have you ever experienced new or inexperienced office personnel?

As you can see, we are delegated repetitive tasks to be performed daily. However, how many of these tasks should be delegated to a pharmacist? Depending on who you ask you will get different answers. Therefore, should we develop standards for each area of concern and place responsibility in the hands of the Board of Pharmacy? Is it time for pharmacy to standardize formularies, to standardize tasks (time allocation, technology, personnel requirements) and to take control of our future? We have asked the questions, now it's time for you to let us know your answers by dropping us a line or giving us a call at the Maryland Pharmacists Association. WE NEED YOUR INPUT AND INVOLVEMENT TO PUSH PHARMACY FORWARD INTO THE NEXT MILLENNIUM.

"Celebrate the Future of Pharmacy"

The 1997 MPhA Mid-Year Educational Seminar

Sunday, February 23, 1997

Loews Annapolis Hotel · Annapolis, Maryland

About this Event

The MPhA Mid-Year Meeting is the must attend gathering of pharmacists! It's an opportunity to learn from and network with other pharmacists in a relaxed and enjoyable environment. This year's program includes a review of new drugs and therapies as well as special presentations on the future of health care and pharmacy.

Registration

Early registration for this 5.5 credit program is $60 for MPhA members and $70 for nonmembers. To register, complete the registration form below and return it to MPhA. Questions? Call us at (800) 833-7587 or (410) 727-0746.

Learning Objectives

At the conclusion of this program, the attendee will be able to:

- Recount the historical forces affecting America's health care system and which forces will continue to affect the future of that system.
- List factors which contribute to medication errors and measures which can be taken to reduce the chance of medication errors.
- Describe the pharmacology and therapeutics of new drug entities released in 1996.
- Describe the therapeutic use of new drug entities in community and institutional practice settings.

Program

8:00 a.m.	Registration and Continental Breakfast
8:30 a.m.	President's Welcome Ernest Testerman, P.D., MPhA President
8:45 a.m.	"Prescription Benefit Managers in 1997" Gail Rosen Spahn, Pharm. D.
9:45 a.m.	"Understanding & Preventing Medication Errors" USP-Trained presenter to be announced
11:15 a.m.	Presentation by Board of Pharmacy Candidates Alisa Billington, P.D., Moderator
12:00 p.m.	Buffet Luncheon
1:00 p.m.	New Drugs and Therapies Babette S. Duncan, Pharm. D. Director of Clinical Services Advance Paradigm Clinical Services, Inc. Joseph D. Ober, Pharm. D. Director of Disease Management Outcomes Advance Paradigm Clinical Services, Inc.
4:15 p.m.	MPhA House of Delegates Business Session

- -

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February 23, 1997
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For more information: (410) 727-0746 (800) 833-7587.

Attendees requesting a refund before February 3, 1997 will be charged a $25.00 administrative processing fee. No refunds will be given after February 3, 1997.

Executive Director's Column

State Professional Associations - Not Just For Breakfast Anymore

Tracy L. Baroni, R.Ph., J.D.
Executive Director

The orange juice people were really onto something when they coined the phrase "not just for breakfast anymore". It is a phrase which can be applied to any number of real life situations. In my mind, breakfast is what preceptor pharmacists provide to pharmacy students. Over 400 licensed pharmacists in the State of Maryland serve as preceptors to University of Maryland pharmacy students. As a preceptor, a pharmacist attempts to nourish the student by giving them the knowledge needed to go out and work in the pharmacy profession. The information provided to students goes beyond the basics of cereal and milk, auxiliary labels and safety caps. The practicing pharmacist gives to the student the wisdom acquired in years of practice, the "ins and outs" of how to be not just competent, but a good pharmacist. The knowledge and training provided is far beyond the realm of breakfast.

The initial years of practice are critical for young pharmacists - the overwhelming desire to find a position which pays well after years as a starving student sometimes conflicts with the desire to find a position which is more than just a job. As MPhA members, students and young pharmacists have access to information and resources to assist them through what can be a confusing and hectic time. Assistance which includes not only cereal and milk, but also toast, fruit, and juice. Unfortunately, these initial years as a pharmacist are not the last critical years facing a pharmacist. The aforementioned desires continue throughout professional life. The changes occurring in the health care system affect every pharmacist every day, whether it is by increasing workload or decreasing reimbursement, by requiring more documentation of intervention or by changing the extent of pharmacy services covered by insurance companies.

And, here it is, back again like any good advertising slogan. Membership in MPhA, while a good beginning, is not just for breakfast anymore. MPhA membership gives pharmacists, young and old, the resources to address and adapt to change. And, like it or not, the reality is that failure to access the resources available could change not only the way you handle a busy day, but your entire career.

Reasons To Renew Your MPhA Membership - Toast, Fruit, and Juice

Sure, you could join a national association, and actually, I strongly recommend it. But, like your State Senators and Representatives, who do you think better understands your needs and concerns, a national association or a state association? MPhA provides:

The Maryland Pharmacist and MPhA Newsletter, published bi-monthly and monthly, respectively. In the recent past, these publications have dealt with issues which include the revisions to the Pharmacy Practice Act, new third party plans, new federal laws, settlement of the discriminatory pricing lawsuit, and recent policies and decisions from the Board of Pharmacy.

A way to network with pharmacists in different locations and different practice settings, both hands-on and through other State Pharmacy Associations. Members have the unique opportunity to meet and develop professional relationships with practitioners in all types of health care settings. By planning and acting together, pharmacists can utilize a combination of knowledge and experience to benefit not only the profession, but also patients.

Specialized Education and Training, in an effort to prepare for pharmacy's future. Year after year, the MPhA Mid-Year Meeting offers up-to-date continuing education which no practicing pharmacist can afford to miss. The 1997 Annual Convention will include a "Pain Management Focus" which will give participants the opportunity to better understand the diagnosis and treatment of acute and chronic pain, as well as other pertinent continuing education offerings. With the passage of the Practice Act revisions, MPhA will offer various courses to assist pharmacists in updating their practices to provide pharmaceutical care.

Pharmacy Laws and Regulations Governing the Practice of Pharmacy in Maryland, a copyrighted publication available to members at a discounted price. Once the entire compilation is purchased, annual updates are available, with the cost of these discounted for members as well. The proposed revisions to the Pharmacy Practice Act have the potential to drastically change the laws which define the what and how of pharmacy practice in Maryland. All parts of the revision passed during the 1997 Legislative Session will be included in the 1998 edition.

A toll-free hotline to answer the practice - related questions of members. Due to the very nature of a professional association, the resources available to MPhA are greater than those available to individual practitioners. If the question or concern cannot be answered based on MPhA's resources, every effort will be made by the MPhA staff to acquire the information needed by the member in a timely manner.

Representation on Pharmacy and Health-Care Issues on both a regulatory and legislative level. The unique position of MPhA enables the Association to more effectively assert the position of its members than do national or specialty associations. As MPhA's Executive Director, I attend every monthly meeting of the Board of Pharmacy, and also participate on behalf of MPhA on various committees comprised of pharmacists and other health care professionals. Regulations which affect pharmacists, both directly and indirectly, are influenced through the actions of MPhA and its Legislative Committee. MPhA has been actively involved in the revision to the Pharmacy Practice Act, and will continue this involvement throughout the 1997 Legislative Session.

Other Services and Programs available as membership benefits. MPhA members are eligible for discounted registration fees for Association meetings and programs. The Association has entered into group agreements with AT&T to provide business-rate discounts, with Alamo to provide discounts to members, and with the Motor Vehicle Certification Program to provide its services to members. Benefits to be offered in 1997 tentatively include an MPhA-MBNA Visa Card and discounted professional liability insurance.

Your Profession - Not Just Breakfast, but Lunch and Dinner, too

Your success in the pharmacy profession, as in anything else, cannot be attributed to one factor. But, like breakfast to the beginning of a productive day, like preceptors to eager pharmacy students, MPhA membership is a good start. If you have not already done so, renew your MPhA membership today. A 1997 Membership Investment Form is included on page 8. Enjoy your toast, fruit, and juice, then move on to lunch and dinner. Utilize the resources and services of MPhA, contact the MPhA offices with your concerns, volunteer for MPhA committees, and participate in the decisions which will effect pharmacy in the next millennium. MPhA is ready, willing and able to assist you through the day, the year, the century.

1997 Membership Investment Form

Maryland Pharmacists Association

Joining your state professional society is as simple as checking a few boxes. Just complete **both** sides of this Membership Investment Form, and drop it in the mail to MPhA at 650 West Lombard Street, Baltimore, Maryland 21201-1572. It's that easy! One year's dues payment brings you a year of benefits!

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Membership Dues

Dues for January 1 to December 31, 1997

Maryland Pharmacists Association

Category	Dues
N-Pharmacist Member	$ 175.00
or	
P-Owner/Manager Member	$ 260.00

An additional $15 has been added for membership in your local pharmacist association:

Please indicate you local association below.

Total Dues ____________

Voluntary Contributions

Give to one, two or all...

☐ **Pharmacists Rehabilitation Committee** $15
Supports chemically impaired pharmacists with recovery and advocacy resources.

☐ **MPhA Scholarship Fund** $15
Provides for MPhA's scholarship program for University of Maryland pharmacy students.

☐ **Kelly Memorial Fund** $10
Helps maintain the MPhA headquarters and B. Olive Cole Pharmacy Museum.

☐ **MPhA Survival Fund** $25
A defense fund established for legal action necessary to protect the profession's interests.

Total Contributions __________________

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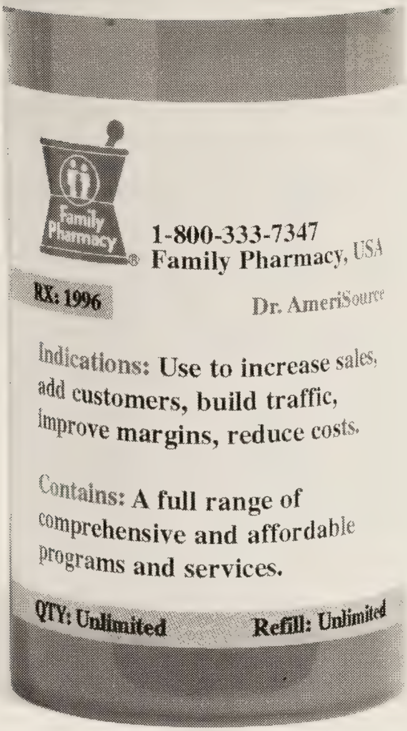
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Communication 101 - On a Legislative Level

Tracy L. Baroni, R.Ph., J.D.
Executive Director

I know it's not normal, but I find the legislative process fascinating. Ever since the Saturday morning cartoon-break musical lesson, "I'm just a bill, on capitol hill . . .", I've wanted to be involved with the who and what behind the laws that govern the lives of mainstream Americans. (For those of you who don't remember the musical ditty, trust me, it was intensely thought provoking to the mind of a seven year-old.) And now, here I am. Who said be careful what you wish for, you may get it?

The 1997 Legislative Session in Annapolis will undoubtedly bring a wide range of issues to the attention of Maryland Senators and Representatives. Whether it's poker machines and gambling or reimbursement for diabetic supplies and training, education is the name of the game. Educated supporters who work to educate and inform legislators can help a bill pass, uneducated opposition and legislators can kill a bill.

As a pharmacist interested in the passage of the three bills encompassing the revisions to the Pharmacy Practice Act, you should be educated on how and why the changes proposed will effect you and other pharmacists practicing in similar practice sites. To obtain a copy of the current draft of the revisions, contact the Board of Pharmacy at (410) 764 - 4755. Once you receive your copy, make sure you understand what the revisions include - anything in capital letters is new language being added to that section, anything between brackets is language being removed from that section. For those people who are unable to stay awake to wade through all the signs, symbols, and "secret legislative code" of the draft, an executive summary and a background section summarizing the proposed changes are available upon request. Questions concerning the draft are best directed to the Board of Pharmacy.

Now it's time to educate the legislators through meetings, letters, and telephone calls. Important things to remember when communicating with legislators are as follows. Always identify yourself as a constituent and pharmacist. Be concise and well organized; ideally, you should be able to present your views in 10 minutes or less. When possible, give real life examples of the effect certain proposals will have on your practice setting and/or patients. Listen to the legislator's comments, questions, and concerns; a meeting is an exchange of ideas, not a speech. A one page summary of key points should be included as part of any communication. Again, succinct points, not threats, are the way to get the attention you want.

Proper form is always important. "The Honorable" should precede the legislator's full name on the envelope and on the inside address. Senator/ Delegate Last Name is the appropriate way to begin a letter or to address the legislator in conversation. Don't forget to use your letterhead - personal or business, it doesn't matter, your identity as a constituent is what counts. Follow up every meeting with a thank you letter and any information requested by the legislator.

Each bill submitted during the 1997 Legislative Session will be assigned to a House subcommittee and Senate subcommittee for initial hearings. A bill which passes the subcommittee hearing will then be heard in the committee. Upon passing the committee, the entire legislative body - House or Senate - votes on the bill. A bill which is defeated in the subcommittee will not be heard in committee and is considered dead for that session.

The bills encompassing the Pharmacy Practice Act revision will be heard by the Health and Public Utilities Subcommittee of the House Environmental Matters Committee and the Economic and Environmental Affairs Health Subcommittee of the Senate Economic and Environmental Affairs Committee. Following is a list of legislators who are members of those subcommittees. Please take the time to meet with or write to those legislators representing your personal residence or the location of your practice site.

Health and Public Utilities Subcommittee

Delegate Brian McHale, Chairman
801 Light Street
Baltimore, MD 21230
(410) 244-8404
District: 47; Zip Codes: 21230, 21228, 21229

Delegate Ronald Guns
107 Railroad Avenue
Elkton, MD 21921
(410) 392-4422
District: 36

Delegate Donald B. Elliott
Box 370
204 Lambert Avenue
New Windsor, MD 21776
(410) 848-5373
District: 4B; Zip Codes: 21776, 21777,
Emittsburg, Mt. Airy

Delegate Peter Hammen
316 House Office Building
Annapolis, MD 21401
(410) 841-3303
(410) 342-3142
District: 46

Delegate James W. Hubbard
13305 Gallery Court
Bowie, MD 20720
(301) 464-6326
District: 23

Delegate Jocob J. Mohorovic, Jr.
1947 Midland Road
Baltimore, MD 21222
(410) 284-5253
District: 7

Delegate Dan K. Morhaim
8 Park Center Court, Suite 100
Owings Mills, MD 21117
(410) 581-8712
District: 11

Delegate Shirley Nathan-Pulliam
(410) 265-5850
District: 10

Delegate Nathaniel T. Oats
314 Row House Building, Rm. 314
Annapolis, MD 21401
(410) 841-3283
District: 41

Delegate Alfred Redmer, Jr.
(410) 841-3365
District: 8

Delegate Paul S. Stull
2813 Raleigh Road
Walkersville, MD 21793
(301) 898-9345
District: 4A

EEA Health Subcomittee

Senator Paula Hollinger, Chair
206 James Senate Office Bulding
Annapolis, MD 21401
(410) 841-3131

Senator David R. Craig
211 N. Washington Street
Havre De Grace, MD 21078
(410) 273-6667
District: 34

Senator Paul G. Pinsky
Senate Office Building, Room 303
Annapolis, MD 21401
(410) 841-3155
District: 22

Senator Perry Sfikas
6006 Eastern Avenue
Baltimore, MD 21224
(410) 631-7900
District: 46

Senator Leonard H. Teitelbaum
205 James Senate Office Building
Annapolis, MD 21401
(410) 841-3151
District: 19

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In the November / December 1996 issue of the *Maryland Pharmacist*, the article "Malnutrition in the Elderly: The Social, Medical and Psychological Risk Factors" was written by Michael Garvin. There was an error in the spelling of Mr. Garvin's name. We apologize.

The Baltimore Veterans Druggists' Association is looking for retired pharmacists to join their active membership. If you are interested, contact Abe Glaser at 410-486-7501.

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Management in the Pharm.D. Program

David A. Knapp, Ph.D., Dean
University of Maryland School of Pharmacy

One goal of our doctor of pharmacy curriculum is to provide students with competencies to provide, coordinate, and manage pharmaceutical care in a variety of practice settings. Thus, all students are required to complete a set of courses that includes required courses in Personal Management and in Practice Management. Personal Management introduces students to organizational theories of management and leadership styles. Included are techniques that assist individuals in managing themselves, such as time management, conflict resolution, and change management. Practice management focuses on the operations management of a business of pharmacy including accounting, purchasing, inventory control, and quality assurance.

In addition to the required portion of the curriculum, about 22% is reserved for electives to allow each student the opportunity for flexible programming. Students may elect to follow a "pathway" or a set of courses, some required and some elective, designed to follow a plan of study in a particular area. Students use these pathways to enhance their practice of pharmaceutical care or to focus on a particular area to better prepare them for their professional career or for graduate studies. Pathways are developed and approved by faculty.

The Management Pathway

The School implemented a management pathway in 1995. It consists of the two required courses described above, three core electives (see below), other electives (Business Plan Development, Integrated health Care Systems Management, Pharmacy Economics) and an Experiential Elective (Pharmaceutical Organizational Management). Students enrolled in the Experiential Elective will spend four weeks in a management rotation such as publications, public relations, or marketing. One state organization, MPhA, has agreed to participate in the program and preliminary contacts have been made with national organizations such as APhA, ASHP, AACP. Corporate clerkships are also being developed.

At a recent Educational Advisory Committee meeting, an overview of the pathway was presented to committee members. The management pathway was developed to allow students to enter management careers in corporate pharmacy, to develop entrepreneurial capabilities, or to prepare them for acceptance into specific residencies or MBA programs. There are 15 students now enrolled in the pathway. The core electives include:

Organizational Behavior. The purpose of this course is to convey concepts and theories of organizational behavior (i.e., the individual, interpersonal, and organizational processes taking place in the workforce and their impact on organizational effectiveness) and to develop team work, problem solving, communications, and life-long learning skills. The format of the course includes lectures, videos, student presentations, research assignments, and case studies. Regina F. Bento, M.D., Ph.D., Assistant Professor, Merrick School of Business at the University of Baltimore, is the coursemaster.

Financial Reporting, Analysis, and Strategy. The purpose of this course is to explain the basic financial and managerial accounting principles so students can learn how to make informed business decisions. Students take exams, write summaries of reading assignments, and do written and verbal reports of group projects. Dana A. Forgione, Ph.D., Associate Professor, Merrick School of Business at the University of Baltimore, is the coursemaster.

Marketing. This course identifies changes in and ways to adapt to an organization's marketplace by using the "market orientation concept" (customer needs, integration of the firm, and profit potential). The coursemaster, Dennis A. Pita, Ph.D., Associate Professor, Merrick School of Business at the University of Baltimore, requires students to complete an analysis (both written and oral) of an important issue in the pharmaceutical industry along with case studies and a final exam.

Pharm.D./MBA Program

Realizing that a pharmacy background coupled with business management expertise is a valuable tool in today's market, the School has entered into an agreement with the University of Baltimore, Merrick School of Business, to initiate a Pharm.D./MBA degree program. Pharm.D. students taking the management pathway will be well positioned to move into the joint program, attaining both degrees in less time than earning the two degrees separately. Maryland students must apply to the University of Baltimore and pay its tuition charges and student fees. Pharmacy students who complete the management pathway fulfill requirements for 21 out of a total of 51 credits toward the MBA degree. Anyone interested in learning more about the Pharm.D./MBA program should contact Dr. William Kinnard at 706-0330. Questions about the M.B.A. admissions procedure may be directed to Ms. Judy Sabalauskas at 837-4944.

Management in the Nontraditional Pharm.D. Pathway

Students enrolled in the Nontraditional Pharm.D. Pathway also take management courses as part of the curriculum. The management component of this program provides students with management knowledge and skills to facilitate the implementation of pharmaceutical care in their practice. Students take a four-credit course entitled Practice Management which is comprised of four different modules: Organizational Management, Pharmaceutical Care Service Management, Marketing, and Finance. The modules are designed to round out the practice skills of the students while preparing them for the practice management experiential component. This component consists of a two-credit course, Practice Management Planning, and satisfies part of the experiential requirements. In this course, students put to work their newly acquired skills to work in developing a business plan for the implementation of a pharmaceutical care project. To date, many of our students have implemented these plans in their own practice with great success! Questions about the Nontraditional Pathway and its management electives may be obtained from Dr. Lynn McPherson at 706-0761.

Our faculty realize the importance of management and entrepreneurism and should be acknowledged for the many hours of work spent to develop and implement this initiative.

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A Piece of Pharmacy History:
Show Globes

Jaime McGee, Pharm.D. Candidate
University of Maryland

Have you ever wondered how show globes became a common symbol of pharmacy and what pharmacists used show globes for in the past? Before I began to research show globes, I thought these large glass bottles were only used for decoration in pharmacies. I was also not aware how much controversy surrounded the origin of the show globe. As you read this article, you will find that many fascinating theories have been proposed about the origin of the show globe.

Show globes are one of the most fascinating and colorful symbols of pharmacy. Through history, pharmacists always prided themselves in their ability to create and maintain brilliantly colored liquids in these globes. The origin of these distinctive bottles as symbols of pharmacy is controversial and dates back four centuries. Unlike the mortar and pestle, the show globe was not a universal symbol of pharmacy. Its popularity was limited largely to "Anglo-Saxon" countries such as Great Britain, the United States, and Canada. The exact cause for the introduction of the show globe as a pharmacy symbol is not well documented. Many stories have been proposed to explain the emergence of the show globe as a symbol of pharmacy.

The most romantic and unrealistic explanation dates the globes to Julius Caesar's invasion of Ireland. It has been stated that Caesar sent an advance party of forces to locate the best landing site. The site selected was opposite an apothecary's shop that had large glass containers filled with colored liquids that were undergoing the process of maceration. Caesar's people guaranteed the pharmacist personal safety if he would place lighted lanterns behind the glass containers to help guide the landing forces during the night. The invasion was successful and Caesar declared that henceforth all apothecaries would be allowed to display large glass containers filled with colored liquid to identify their establishment. Unfortunately no evidence has been found to substantiate this story. In fact, no recognizable separate profession of pharmacy was practiced until twelve centuries after this incident was supposed to have occurred.

Another unlikely explanation places the origin of show globes in the Middle or Near East during the Islamic domination. This story explores a connection between the show globes and the glass vessels and jars filled with colored liquids or substances that surrounded the open-front of the pharmacists' shops. Although an interesting story, if it were true, why were show globes adopted as signs of pharmacy primarily by England and British-influenced areas and not by Italy and Spain, both of which had closer relations with the Middle East?

The same question arises when considering the theory that show globes originated as derivations of the vessels used for maceration of crude drugs. These vessels were often 2-3 gallons in size and kept in the front window of the pharmacy. However, maceration was a universal process and was not restricted to England. Also, the windows of the pharmacies until the early nineteenth century were relatively small and the streets were narrow. Most likely maceration vessels were exposed to the sun in the backyards of the pharmacies rather than in the front window of the shops.

Another theory is that apothecaries in coastal towns of Britain displayed green and red globes in their window. They arranged these globes to mimic the shape of a ship's running lights. The apothecaries used the globes as advertisement for first aide to sailors who may have been injured during waterfront brawls. British apothecaries offered surgical services along with pharmaceutical services until around the eighteenth century. If English apothecaries displayed show globes in such a way, they did so as surgeons, not as pharmacists. This theory is possible, but it does not explain why an advertisement for medical services evolved into a pharmaceutical symbol.

The theory which historians most accept dates the origin of the show globe back to England in the mid 1500's when three separate professions, the apothecaries, the druggists, and the "chymists" all dealt with dispensing drugs. Apothecaries specialized in delivering surgical services along with compounding and dispensing herbal medicines, they did not deal in chemical drugs. Druggists bought drugs in bulk and sold them for retail. Chymists prepared and sold chemical preparations used for medicinal purposes, such as mercurials. In continental Europe, chymists were looked upon with suspicion and forced to practice chemistry underground. However, in England the chymists practiced openly and were officially recognized by the Royal College of Physicians in 1553, along with the apothecaries and the druggists. The chymists wanted to distinguish themselves from the apothecaries and chose to use the globular or pear-shaped glass vessels with elegantly ground glass stoppers as a symbol of their trade. These vessels were originally known as carboys and were used by the chymists for the transport of acids and other liquids. They adorned them with gold leaf symbols to identify the contents of the carboys. The chymists began to display these bottles in their windows. The bottles were filled with brilliantly colored liquids and illuminated by lanterns at night. They were so beautiful at night that Charles Dickens once declared they were the only "bright and cheery spot" in a London street on a dark and wet night. The chymists merely chose a tool of their trade as a symbol of their profession, much like the adoption of the mortar and pestle as the symbol of the apothecaries. This account could explain why the show globe has mainly been a symbol of pharmacy in Anglo-Saxon countries, but it still does not explain why pharmacy adopted a chemistry symbol.

It has been suggested that the growing interest in chemical medicines forced the apothecaries, first in London and later in the rest of the country, to begin preparing chemical medicines themselves. These apothecaries had to make it known to the public that they too were preparing chemical medicines, therefore, they adopted the chymists symbol, the show globe. Furthermore, it is believed that the Great Plague in London caused the London apothecaries to display illuminated show globes filled with red liquid to direct the sick to the apothecary shops to receive medical care. Many physicians had fled London or died during the Great Plague (1665-66) which left most of the medical care in the hands of apothecaries.

The English apothecaries began to expand as medical practitioners after the Great Plague. They had been fighting to gain the right legally to practice medicine and prescribe to patients. In the early eighteenth century the apothecaries won this battle. After this expansion of their profession, they gave more attention to their medical duties than to their practice of compounding and selling drugs. The apothecaries had never intended to relinquish the practice of pharmacy. However, by the end of the eighteenth century, the druggists and chemists began to absorb most of the compounding and dispensing of drugs. By the early 1800's, chemist & druggists practically monopolized the practice of pharmacy. As a result, the old English apothecary evolved into a medical practitioner while the chemist and druggist became the heirs of the practice of pharmacy.

Another theory for why the apothecaries adopted the show globe as a symbol of pharmacy was as a sign for bloodletting, which at the time was believed to be a cure for almost any ailment. Apothecaries that offered the service of bloodletting were said to have placed show globes filled with blue and red colored liquid in their windows to represent venous and arterial blood. Again, the show globes were said to have been used as an advertising device.

By the third quarter of the eighteenth century, glass manufacturers began to create more decorative carboys or show globes. It is documented that show globes were imported to the United States as early as 1789. However, these globes were not advertised in American pharmacy catalogs

until the mid 1800's. American glass manufacturers helped evolve the show globes from simple English carboys to diverse and elaborate multi tiered pieces of art. The globes became double and triple tiered and made of etched and cut glass.
Pharmaceutical catalogs during the 1870's advertised numerous styles of show globes. Practically each American glass manufacturer developed their own specialized style of show globe, the most noted being the "Pine Apple Globe" by F. Hale of 48 Beekman St., New York. The interest in show globes became so widespread that a U.S. patent was granted to Henry Whitney of E. Cambridge, MA, on March 23, 1869 (No. 88,105). Mr. Whitney designed a unique show globe that had a colored glass body with a neck and base of transparent uncolored glass. This design was to eliminate the need to use colored liquids, which could leave a residue inside the bottle.

Though attempts have been made periodically to repopularize show globes, they have disappeared from most pharmacies in the United States today. Through the centuries the show globe has remained a popular symbol of pharmacy. Many beautiful and rare examples of various styles of show globes can be found in the B. Olive Cole Museum at the Kelly Memorial Building.

Formulas for Colors for Show Globes:

Red

Iodine	2 Gm
Potassium iodide	2 Gm
Hydrochloric acid	36 ml
Water	960 ml

Dissolve the iodine and potassium iodide in water and add the hydrochloric acid. Mix.

Blue

Copper Sulfate	14 Gm
Alum	14 Gm
Sufuric acid	13 ml
Water	473 ml

Dissolve the alum and copper salt in water, add the sulfuric acid in small portions, and filter.

Dark Blue

Copper Sulfate	10 Gm
Ammonia Water	40 ml
Water	950 ml

Dissolve the copper sulfate in a small amount of water. Add ammonia water until the precipate first formed is just redissolved, then add the remainder of the water.

Green

Copper Sulfate	7 Gm
Ammonium Chloride	7 Gm
Water	186 ml

Many shades of permanent green may be produced by adding Solution of Ferric Chloride in varying quantities to the above.

Orange

Potassium Dichromate	4 Gm
Nitric Acid	1 ml
Water	120 ml

Dissolve the potassium dichromate in the water and add the nitric acid. Mix.

Purple

Salicylic Acid	1 Gm
Alcohol	93 ml
Ferric Chloride Tincture	4 ml
Water, as may be desired	

Dissolve the acid in the alcohol. Add the tincture and dilute until desired color is produced.

Yellow

Potassium Dichromate	1 Gm
Nitric Acid	2 ml
Water	27 ml

Dissolve the potassium dichromate in the water and add the nitric acid, filter.

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NUTS AND BOLTS - FROM THE BOARD OF PHARMACY

In the past few months, even with the hustle and bustle of the holidays, for the Board of Pharmacy it has been business as usual. During the public sessions of the October and November Board of Pharmacy, the Board addressed several pertinent questions and concerns.

The Board of Pharmacy agreed to sponsor the USP-developed program "Understanding and Preventing Medication Errors" at the MPhA 1997 Midyear Meeting scheduled for February 23, 1997 at Loewes, Annapolis. The program is ACPE approved for 1.5 credit hours. The program will also be used by the Board as required CE for pharmacists called to the attention of the Board as a result of making an unusually high number of errors.

The Board Composition Bill scheduled to be submitted in the 1997 Legislative Session will expand the Board of Pharmacy to include ten pharmacist members. According to the draft bill, the pharmacist members will be from a variety of practice settings, including 2 independent community, 2 chain community, 2 acute care hospital, 1 long term care, 1 home infusion, and 2 at large. Designated seats helps to assure that the Board of Pharmacy members will possess a wide range of experience to deal with an ever-growing field of issues and questions. Under the bill, pharmacists whose primary source of employment comes from a school of pharmacy may serve as Board members, but will be recused from all aspects of the examination process.

McKesson's CareMax program was reviewed by the Board of Pharmacy at its October 17, 1996 meeting. Several representatives from McKesson and independent pharmacies throughout Maryland were present to discuss the Board's concerns.

The CareMax Program utilizes a data processing service owned and operated by McKesson to assist pharmacies in third party reimbursement and other areas of community pharmacy practice. The pharmacy's prescription files are retrieved and correspondence pertaining to prescriptions filled is sent to the patient by McKesson on the letterhead of the pharmacy. The types of correspondence sent to patients include refill reminders, recommendations for therapeutic interchange of a drug being taken by the patient, and OTC tie-in sale letters based on the patient's therapy.

Based on confidentiality issues, the Board recommended that any CareMax participating pharmacy obtain a written waiver from any patient whose prescription information would be processed through CareMax. Additionally, the Board will forward the issue to the Attorney General for an opinion.

NUTS AND BOLTS

At the October 17, 1996 meeting, the Board considered the interchangeability of Levothroid and Synthroid. The FDA has not evaluated Levothroid as being bioequivalent to Synthroid (AB rated), and therefore neither of the drugs can be legally substituted for the other, absent the consent of the prescriber. A pharmacist who makes a substitution of these drugs without consent of the prescriber (even though the substitution is required by the patient's insurance) could be held liable for injury experienced by the patient as a result of the substitution. The lesson? Make the call!

The Board voted to accept the 23 candidates for reciprocal licensure who met with George Voxakis on October 15, 1996 and the 18 with whom he met on November 12, 1996.

At its November 13, 1996 meeting, the Board reviewed the first quarter report, covering July through September 1996. Since the Board is not charging pharmacists for license renewal for 1996 and 1997, funds must be monitored closely to assure that the budget carryover is equal that projected.

Based on the report, first quarter revenue and expenditure levels indicate a projected total carryover of $900,000 by the end of fiscal year 1997 and a total carryover of $750,000 at the end of fiscal year 1998. These totals may make possible the initiation of the Maryland Poison Center media campaign in FY 1997, rather than in FY 1998 as previously planned.

Sixty-four candidates sat for the various licensure exams given by the Board in September, 1996. Of the 36 candidates taking NABPLEX, 30 passed the exam. Thirty-seven candidates took the Maryland Law exam, and 25 passed. All 32 candidates taking the laboratory portion of the exam passed, and all four candidates for licensure reinstatement passed the Board's Reinstatement Exam.

The Board is in the process of developing a written law exam to be given to pharmacists applying for reciprocal licensure.

Maryland Board of Pharmacy 1997 Board Meeting Schedule

January 16, 1997	Room 109
February 19, 1997	Room 109
March 19, 1997	Room 109
April 16, 1997	Room 215
May 21, 1997	Room 109
June 18, 1997*	Room 109
July 16, 1997	Room 109
August 20, 1997	Room 109
September 17, 1997	Room 109
October 15, 1997	Room 109
November 19, 1997	Room 215
December 17, 1997	Room 215

The public session of all meetings begins at 8:30 a.m. All meetings are held at 4201 Patterson Avenue, Baltimore, Maryland 21215.

* Due to a conflict with the MPhA 115th Annual Convention, this meeting will be re-scheduled.

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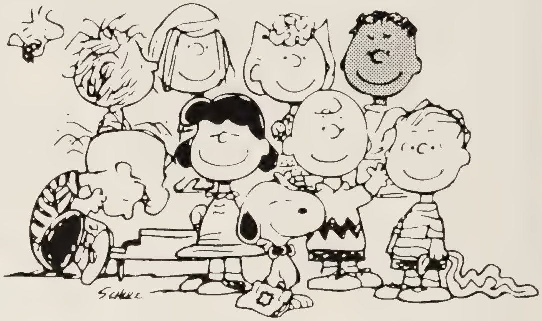

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Board of Pharmacy Candidates

Phyllis M. Bartilucci, M.S., R.Ph.
701 E. Charles Street
P.O. Box 1070
La Plata, MD 20646

Graduated 1975 B.S. Pharmacy
St. John's University
College of Pharmacy and Allied Health Professions

Graduated 1977 M.S. Pharmacology
St. John's University
College of Pharmacy and Allied Health Professions

Current Practice Setting:
Inpatient Institutional Pharmacy

If appointed to the board, I will bring a unique perspective on the practice of pharmacy. While my career has primarily been in the hospital arena, culminating in my present position as Director of Pharmacy at Physicians Memorial Hospital, I have had experience in retail, education and consulting.

My distinctive background, as the daughter of a pharmacy school dean and former member of the New York State Board of Pharmacy, sister-in-law of a retail pharmacist/owner and my various work experiences provide me with insight and an open mind with which to tackle the business of the Board. I will draw on my experiences and shared family experiences to best represent all the pharmacists of Maryland.

I will bring to the Board an interesting and unique perspective on the practice of pharmacy, which will be useful to consumers of pharmacy services and my fellow pharmacists.

Bernard J. "BJ" Lechman, P.D.
1815 Bedford Street
Cumberland, MD 21502

Graduated 1960, B.S. Pharmacy
Duquesne University School of Pharmacy

Current Practice Setting:
Chain Community Pharmacy

I have been a licensed pharmacist since 1960, and have held a Maryland license since 1965. My work experience includes chain pharmacy as well as hospital pharmacy. I have served as Chairman of the Great American Smoke-Out and as a board member of the American Cancer Society in Allegany County, Maryland, and also served on the Finance Committee of the American Cancer Society.

I am proud to be a member of the pharmacy profession and serving on the board would be the zenith of my career. Thus, I will serve with the honesty typically exemplified by the Maryland Pharmacists with whom I have dealt. Your support in this endeavor to serve on the Board of Pharmacy would be greatly appreciated.

David B. Liebman, P.D.

12 Swanhill Drive
Baltimore, MD 21208

Graduated 1961 B.S. Pharmacy
Medical College of Virginia, School of Pharmacy

Graduated 1970 M.S. Hospital Administration
Medical College of Virginia

Graduated 1976 M.S. Public Administration
Nova University

Graduated 1977 Ph.D. Public Administration
Nova University/New York Institute of Technology

Current Practice Setting:
Independent Community Pharmacy

I have been a practicing pharmacist for over 35 years in a variety of settings as both an employee and employer. I have worked in hospitals, large and small, as well as for chains and independents.

I have seen our profession evolve through a number of changes, some good and some not so good. Through all these changes over the years, one thing has remained constant. I still enjoy being a pharmacist, love what I do, and look forward to going to work.

I strongly believe that pharmacy is the first line of defense in health care.

I would like to bring my experience and enthusiasm to the Board of Pharmacy.

Walter P. "Bill" Mackay, R.Ph., M.B.A.

264 Armstrong Avenue
P.O. Box 496
Frostburg, MD 21532

Graduated 1962 B.S. Pharmacy
University of Maryland, School of Pharmacy

Graduated 1995 M.B.A.
Frostburg State University

Current Practice Setting:
Inpatient Institutional Pharmacy

I am seeking the post of Board Commissioner as an opportunity to serve my profession. If selected for the position, I will serve in the best interest of the pharmacists and citizens of the state.

I have been an actively practicing pharmacist in Western Maryland for over 35 years. During this time I have owned and operated an independent retail practice, provided services to nursing homes and a small hospital, and I am now employed by an acute care hospital as a staff pharmacist. These various practice circumstances afford me an extensive background from which to draw.

I chose, after 29 years, to change my career path completely. I left a successful retail business to become an institutional pharmacist. This transition was similar to an entire re-education since methods and procedures are quite different in the two areas of practice. I welcomed the challenge of the new pathway in my occupation and felt that the challenge was well worth the effort.

If I am selected for a Board position, I will look forward to serving diligently and performing all duties that are required of the assignment.

Jacob R. Raitt, B.S., M.S., Ph.D.

6905 Scotch Drive
Laurel, MD 20707

Graduated 1956 B.S. Pharmacy
Columbia University, College of Pharmacy

Graduated 1958 M.S.
Ohio State University

Graduated 1960 Ph.D. Pharmacology
Ohio State University

Current Practice Setting:
Independent Community Pharmacy

All of these candidates are qualified for the positions on the Board of Pharmacy which we seek. No one lacks the requirements of the positions, either in scholastic or performance achievement, nor in the desire to serve the profession of pharmacy. The choice that you, our colleagues, must make, is among the directions which we believe pharmacy should take, based upon the depth and breadth of our experiences. The true choice is not between candidates -- but rather between avenues of dedication.

My background in pharmacy takes me back to the early 1950's, where ***all*** pharmacists were consultants, and where ***all*** recommendations were "clinical". My background starts in the era of the art of compounding, where medications integral to rational therapy were prepared, not manufactured, --- and extends to being an expert "generalist" versed in "modern" pharmacy. This background makes me unique amongst the candidates, for now pharmacy once more begins to encompass the arena of total consulting as well as rational medication preparation (compounding) -- my areas of strength.

Melvin N. Rubin, P.D.

4001 Old Court Road #419
Baltimore, MD 21208

Graduated 1955 B.S. Pharmacy
University of Maryland, School of Pharmacy

Current Practice Setting:
Independent Community Pharmacy

The Board will consist of four pharmacists with a total of less than seven years experience on the Board after George Voxakis' and Dorothy Levi's terms expire. It can easily take two years for someone to fully understand the complexities of the Board. I hope to be chosen to fill one of those seats and add my five previous years of Board experience, as well as 30 years working for the profession as a member of MPhA and the Alumni Association, having served as president of each. My professional experience includes 13 years with a chain and 30 years owning my own business, including nursing home work.

Most of my efforts through the years have related to the pharmacist, not the pharmacy. If re-appointed to the Board, I would carry out all functions while bearing in mind how the decisions would affect the way the pharmacist can and should serve the patient.

Joseph M. Schuman, P.D.

5905 Key Avenue
Baltimore, MD 21215

Graduated 1955 B.S. Pharmacy
Howard University, College of Pharmacy

Current Practice Setting:
Institutional Inpatient/Outpatient Pharmacy

In this age of technology, many changes are occurring that will affect the future of pharmacy economically, ethically, and professionally. Cut backs and down grades will lower fees and newer medications will demand greater knowledge and compliance by patients and pharmacists. The Board of Pharmacy will be confronted by many challenges such as establishing regulations concerning the "right to die" and the "morning after pill".

A strong, diversified Board will be needed to set the criteria necessary to protect the public and the profession. The board must represent every segment of society, pharmacy expertise, and experience. Due to my varied pharmacy experiences and training, I am eager and well prepared to confront the issues and challenges that lie ahead.

I have forty years of experience in the field since graduation. I passed the Washington, D.C. Boards and served as pharmacist at the United States Naval Hospital in San Diego, at which time I also passed the California Boards. After the Navy, I worked in independent and chain retail pharmacies. Later, I operated my own pharmacy for twenty years and for the past fourteen years I have been the pharmacist in charge at the Maryland Rehabilitation Center.

In my opinion, I have much to contribute to society and to the pharmaceutical industry by serving on the Maryland State Board of Pharmacy.

Belinda M Tilley, Pharm. D., M.S.

9704 Thorncrest Drive
Fort Washington, MD 20744

Graduated 1977 B.S. Pharmacy
Temple University, School of Pharmacy

Graduated 1979 Pharm.D.
Philadelphia College of Pharmacy & Science

Resident in Pharmacy Practice 1980
Philadelphia College of Pharmacy & Science

Graduated 1995 M.S. Business Management
The Johns Hopkins University

Current Practice Setting:
Pharmaceutical Industry

I have a broad experience serving in various positions as a clinician, academician, supervisor, and manager. Over the course of a number of years, I have been responsible for shaping the future of pharmacy by precepting pharmacy students and instructing medical students in the classroom and at the patient bedside. I have made numerous presentations to professional audiences and consumer groups and have published several papers.

Recently, when I worked as Director of Pharmacy at the George Washington University Medical Center, I managed a bustling inpatient and outpatient operation. Because of that experience I understand the delicate balance which must be maintained in preserving high quality patient care, keeping professional and technical staff motivated, and meeting regulatory requirements while remaining fiscally responsible.

I bring twenty years of experience as a pharmacist and want to take a leadership position in shaping the future of the profession.

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Thoughts about Pharmacies in Russia

Phyllis Bartilucci, Director of Pharmacy
Physicians Memorial Hospital, LaPlata, Maryland
Interviewed by: Jaime McGee, Pharm.D. Candidate, UMAB

Q: *In general, what are the Russian people like and how do they live?*

A: The people for the most part are warm, friendly, fun loving, and happy, despite their hard life and bleak living conditions. During the summer months they all try to plant gardens, both flowers for their beauty and vegetables to supplement the family's food supply. Although most of those I met lived in the "city" in "flats" or apartments, they usually had an "allotment" which is a plot of land to be farmed or gardened.

Cars are a relative luxury, people walk or take the bus. Cars were old, driven hard and fast. Roads were not very well kept; there were lots of pot holes. Those who do have cars keep them locked in garages, because car thefts or car-parts thefts are common. I did not see how much the gasoline costs, but did notice that gas stations seemed to be few and far between.

Q: *How did the nutrition and meals in Russia differ from that in the United States?*

A: The food we were served was in many ways different from what I am used to. Like so many other Americans, I am very conscious about my dietary fat intake. The Russians seem to have no such concerns and perhaps this is a big contributor to their short anticipated life span, which for males is 57.

Breakfast typically included a glass of juice, cheese and/or ham or salami, sliced bread, a roll or muffin, and either "bline" (pancakes) served with sour cream and/or syrup, hard boiled egg or an egg dish (quiche or omelette type), coffee and/or tea. Lunch is the main, heaviest meal of the day. Lunch would include a salad (either vegetable salad containing green pepper, tomato and cucumber, coleslaw-type salad, tuna salad, potato salad, or beet salad), hot soup (most days it was a "borchst" based vegetable soup with a dollop of cream in it, although twice we had chicken soup), a main course of meat or fish with potatoes with/without vegetables (often it was a stew-like combination of meat/fish, potatoes, and onions in a cream sauce, although one day we had steamed dumplings) and dessert (vanilla ice cream that was very wonderfully creamy or pastries). Dinner was much like lunch without the soup course.

There was always white and brown/black bread on the table and mineral water. Coffee, tea, Coke®/Pepsi®, or beer were also always available.

Q: *How does the pharmacy profession differ in Russia? How long do you have to go to school to become a pharmacist?*

A: Most (~90%) pharmacists and technicians are female. Pharmacy has not traditionally been considered a prestigious profession and is not well paying. Therefore, it is not so attractive to men. Those men who do enter the field are most likely to work in the retail setting, where there is more opportunity to make money. There are a few "independent" retail pharmacies, but most are government run/supervised.

There are "pharmacefts" which are 2 year school graduates and are similar to our pharmacy technicians. "Provisors" are similar to our pharmacists. They go to school for 5 years. All provisors must take an exam every 5 years to renew their license.

Q: *What are retail pharmacies like in Russia?*

A: Drug stores in Russia are set up as separate "departments." One is for paying customers and those with insurance. These are well stocked and contain prescription and over the counter items, as well as some "health and beauty" items such as toothpaste, shampoo, etc. Another department is used for compounded prescriptions.

Many prescriptions are for compounded items. A third department is for "free" prescriptions, similar to our Medicaid.

All of these "departments" are in the same building, but patients enter different doors depending on which "department" is needed. Items for sale in the pharmacies are displayed behind the counter or in glass-fronted show cases. Other items are depicted in typical advertisement posters and paper displays. No items are out for self-service.

We did go into one department store in Novgorod which seemed pretty well stocked with everything from Gillette® disposable razors to Air Nike® sneakers! Most other shops where the "natives" would shop had little merchandise available for self-service, but was, instead, behind the counter to be obtained through the help of one of those employed by the shop.

Q: *Whose responsibility is it to screen for drug allergies, interactions, and counsel patients about their medications?*

A: Retail and hospital pharmacists do not keep patient profiles either manually or by computer. It is the doctors responsibility to be aware of the medications he/she orders for the patient as far as monitoring for possible interactions. The doctor is also responsible for being aware of any drug allergies the patient may have.

The pharmacist is required by law to include with the prescription some written information regarding the medication, but the doctor is responsible for talking with patients about the medications which he/she has ordered. I asked what type of written information was given to the patient but never really got an answer.

Q: *What are hospital pharmacies like in Russia?*

A: Hospital pharmacies have no money. At Central Hospital in Novgorod, the pharmacy director reported that she had not purchased any medications in four months due to lack of funds. Under the old system, hospitals were high on the priority list for money and supplies were not a problem. Under the new system, retail pharmacies have grown. The retail pharmacies have the money to buy drugs and supplies. When a patient is admitted to a hospital, the doctor writes a prescription which the patient's family fills at the retail pharmacy. The prescription is returned to the patient to use during the stay in the hospital.

Hospital pharmacies still prepare IV solutions and place them in re-used, re-sterilized glass bottles. The used glass bottles are returned from the nursing units/ "departments" to the pharmacy where they are washed and autoclaved before being re-filled and re-capped. The prepared solutions are stored on shelves in the pharmacy until dispensed as requested to the nursing units for patients.

Q: *How does hospital care differ in Russia?*

A: Medicine is practiced very differently there than it is here. When asked what our length of stay was at my hospital, I answered four days. That response was followed by the question: "Then how long do they stay in the hospital after they are discharged from ICU?" I explained that the four day length of stay included time in the ICU if necessary; that patients go home after four days. As an example, in Russia, their myocardial infartion patients spend 10 days in ICU (without ambulation), the next two weeks in the hospital in an ambulation program, then 4-6 weeks in a sanitarium for recovery.

Q: *Will you be returning to Russia in the near future?*

A: The trip was really rewarding and frustrating at the same time. I would love to go back in 5-6 years, but not any sooner because I don't think anything will change that quickly. It was a great experience. For those interested in visiting Russia, the number for the Novgorod Alliance is 703-759-7090. The next trip is planned for the last week in May/ first week in June of 1997. The group tries to make the trip once every year.

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Continuing Education for Pharmacists

Volume XIV, No. 3

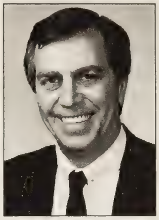
Patient Counseling on Varicose Veins

Thomas A. Gossel, R.Ph., Ph.D.
Dean, and Professor of Pharmacology and Toxicology
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph., Pharm.D.
Professor of Pharmacy Practice
University of Cincinnati
Cincinnati, Ohio

Gossel



Wuest

Goals

The goals of this lesson are to discuss the causes, prevention and treatment of varicose veins, and to suggest information that can be conveyed when counseling patients with varicose veins.

Objectives

At the conclusion of this lesson, successful participants should be able to:

1. identify the factors that predispose, cause, or worsen varicose veins;
2. differentiate between various nonpharmacologic methods to treat varicose veins;
3. exhibit knowledge of the terms *sclerosing agent* and *sclerotherapy,* and identify examples; and,
4. demonstrate an understanding of how to counsel patients on the causes, prevention and treatment of varicose veins.

A professional development program made possible by an educational grant from

SEARLE

Introduction

Most pathologic disorders of the veins do not have the impressive frequency or dynamic outcomes of arterial diseases such as atherosclerosis, aneurysms, coronary heart disease, and cerebrovascular accidents. However, some less common venous disorders can cause extreme discomfort and/or disfigurement. Varicose veins is one such condition.

Veins and Their Valves

The function of the venous system is to return blood from peripheral tissues back toward the heart. Veins are frail structures that depend on the surrounding tissues for their support. They are broadly defined as superficial or deep. Superficial veins are those that are located near the body's surface. They are imbedded in skin and other connective tissue. Deep veins are those which lie deeply within the muscle mass.

In order to understand the causes and treatment options for varicose veins, it is important to first consider the concept of hydrostatic pressure. A reference point for understanding this is to envision a body of water such as a lake. The pressure on the water at its surface is equal to atmospheric pressure, but rises 1 mm Hg for each 13.6 mm distance below the surface. This pressure results from the weight of the water and is, therefore, called hydrostatic pressure. The hydrostatic pressure along the length of the leg, and along the length of the venous return system to the right atrium, decreases proportionally with the distance from the foot to the heart.

A similar event is noted on the vascular system because of the weight of blood in the veins. When a person is standing upright, the pressure in the right atrium is approximately 0 mm Hg since pressure is affected by muscle movement. When the person stands absolutely still, the pressure in the veins of the feet is approximately 90 mm Hg, simply because of the weight of the blood in the veins.

Valves. Most veins that are larger than 2 mm in diameter contain a system of valves which aid in the return of blood to the heart because they are positioned in such a way that they assist the return of blood from areas of the body below the heart, against the force of gravity. These valves are bicuspid in design, meaning that they consist of two tiny folds of tissue (cusps) arising in the vein's inner wall (the intimal layer).

Valves are located at irregular intervals. Their number varies from person to person. There may be up to 20 valves along the long saphenous vein, the primary surface vein that traverses the entire length of the leg. There may be 9 to 12 valves in the short saphenous vein. This runs from the foot up to the back side of the knee. Valves are arranged so that the direction of blood flow can only be toward the heart.

With each movement of the legs, the muscles are tightened and compress the veins located within the muscles and those adjacent to them. This compression squeezes blood upward and out of the veins. If one stands perfectly still, the venous hydrostatic system (pump) does not work, and the venous pressure in the lower part of the leg can rise to the full hydrostatic value of 90 mm Hg in about 30 seconds. Blood can collect in the lower extremities and fluid will leak from the circulatory system into the tissue spaces. As a result, the legs become swollen and the blood volume diminishes. In fact, as much as 15 to 20 percent of the blood volume can be lost from the circulatory system within the first 15 minutes of standing perfectly still, as sometimes occurs when a soldier is forced to stand at absolute attention. In persons engaged in occupations in which they must stand for long periods each day, e.g., pharmacists, such pooling of the blood can eventually stretch the veins and lead to varicose vein development. This is accentuated with heavy lifting.

Valves can become incompetent and are sometimes destroyed. This is especially true when the veins have been stretched beyond a reasonable size by an excess of venous pressure for a prolonged period, e.g., during pregnancy. Stretching the veins increases their diameter, but does not increase the size of the valves. The valves no longer close completely to block the reverse blood flow in the enlarged veins. This increases the vein diameter even more, creating a vicious cycle, i.e., onset of varicose veins.

Etiology of Varicose Veins

By definition, varicose veins are prominent, abnormally dilated, tortuous (marked by repeated twists, turns or bends), and elongated areas in the saphenous veins and their tributaries. They differ from an aneurysm in that in the former, the vessel is affected throughout a significant segment of its length. An aneurysm is more localized to a specific section. Varicose veins usually result from defective structure and function of the venous valves.

Other possible causes include intrinsic weakness of the vein wall, or rarely, from atriovenous fistulas. The high occurrence in the saphenous vein is due to the high venous pressure in the legs when they are dependent (i.e., pointed downward), coupled with the relatively poor tissue support for the superficial veins.

Approximately 20 percent of adults (with up to 50 percent of persons over age 50) are reported to develop varicose veins. A family history of varicose veins is present in up to 15 percent of patients. This is postulated to be due to defective development of the walls of veins. Marfan syndrome, various Ehlers-Danlos syndromes, and an autosomal recessive condition featuring distichiasis (a double row of eyelashes) predispose to varicose veins.

The condition is more common in women than men by a factor of 5:1, probably due to venous stasis in the lower legs during pregnancy. Indeed, most women date the onset of varicose veins from a pregnancy.

Obese persons have a greater tendency to develop varicosities. This probably relates to their poor tissue support resulting from large accumulations of subcutaneous fat.

As stated earlier, varicose veins are dilated, tortuous and elongated. This dilation is irregular, and the vein will show nodular or fusiform (tapering toward the end) distensions, or even aneurysmal pouchings. There is asymmetric variation in the thickness of the vessel wall with thinner sections at points of maximal distension. Compensatory hypertrophy may produce thickening of the vessel wall in a neighboring segment. Frequently, the elastic tissue in the major veins will have degenerated.

Varicose veins are categorized as primary and secondary. A primary condition is one that originates in the superficial venous system. Secondary varicose veins result from deep venous insufficiency and incompetent perforating veins, or from deep venous occlusion causing enlargement of superficial veins that are serving as collaterals.

In most affected individuals, there is no clearly identifiable cause or precipitating factor. Congenitally absent or defective valves are a cause of varicose veins in early life. The cause may be thrombosis secondary to thrombophlebitis (partial or complete occlusion of a vein by a thrombus [blood clot]) or external pressure, as is the case in pregnancy, ascites, and tumors. Individuals with varicose veins in the lower extremities have been shown to have increased venous distensibility and reduced amounts of collagen and hexosamine (a nitrogenous sugar) in the walls of unaffected veins. The role of deficiency of these substances is unclear. An association of varicose veins with hemorrhoids and diverticulitis suggests that increased intra-abdominal pressure during bowel movements may play a role in their pathogenesis.

Veins in at least three sites other than the legs may also become varicosed. One such site of varicosity formation is the venous system at the anorectal junction, which causes hemorrhoids. The cause of hemorrhoids is presumed to be prolonged pelvic congestion resulting, for example, from repeated pregnancies or chronic constipation and straining during bowel movements.

Another site, and a much more acutely important one, is the esophagus. Esophageal varices are found in persons who have cirrhosis of the liver and its attendant portal hypertension. Rupture of esophageal varicosed tissue may be more serious than the primary liver disease itself.

A third site is the spermatic cord. A varicocele (swelling) is the usual outcome. This is a varicosed condition of the veins of the pampiniform plexus (vascular bed in the testicle and epididymis), forming a swelling that feels like a "bag of worms" appearing bluish through the skin of the scrotum and accompanied by a constant pulling or dull pain in the scrotum.

Signs and Symptoms of Varicose Veins

Many times, the condition will be asymptomatic. There is no correlation between size and number of varicosities and intensity of symptoms.

Signs and symptoms characteristic of varicose veins include calf heaviness, dull aching, or pressure experienced on prolonged standing (and relieved by elevation of the limb). The legs feel heavy. With disease progression, dependent edema is noted, and skin pigmentation caused by venous stasis may appear. This edema impairs circulation, rendering the tissues extremely vulnerable to injury.

The clinical significance of varicose veins ranges from innocuous cosmetic embarrassment to venous dysfunction that predisposes to stasis ulceration and thrombus formation. The patient is often concerned most about cosmetic appearance of the legs. Extensive varicosities may cause skin ulcerations near the ankle.

Table 1
Schlerosing Agents for Treating Varicose Veins in the Leg

Generic Name	TradeName/Manufacturer	Availability
Morrhuate Sodium	Morrhuate Sodium/ American Regent, Pasadena	Inj: 50mg/mL
	Scleromate/Palisades Pharm	Inj: 50mg/mL
Sodium Tetradecyl Sulfate	Sotradecol/Elkins-Sinn	Amps: 1%, 3%

Superficial venous thrombosis may be a recurring problem. Rarely, a varicosity will rupture and bleed. While blood clots frequently form within varicose veins, their embolization to the lungs from the superficial leg veins occurs rarely.

Varicose veins are generally visible when the affected individual stands. Although varicose veins can induce significant discomfort and morbidity, the condition is rarely life threatening.

Treatment

The most conservative treatment is *no treatment.* If the deep vein system is healthy, nothing needs to be done.

Sclerosing *(sclero* = hard) agents may be used for treating small varicosities. The varicosed portion of the vein is isolated and blood aspirated from it. A solution of sclerosing agent is injected directly into the vein. Sclerosing agents indicated for treating varicose veins include morrhuate sodium and sodium tetradecyl sulfate (Table 1). Morrhuate sodium is a mixture of the sodium salts of the saturated and unsaturated fatty acids of cod liver oil. Sodium tetradecyl is an anionic surface active agent. Another sclerosing agent, ethanolamine oleate (Ethamolin), is indicated solely for treating esophageal varices.

Sclerosing agents irritate the vein's inner walls to cause inflammation of the vein's innermost endothelial cell lining and formation of a thrombus. The thrombus occludes the vein and closes it off, and fibrous tissue forms. A pressure bandage should be applied to the leg after injection to compress the vein's walls together and prevent blood flow through them. This is continued for at least six weeks. The shrunken vein remains in the leg, and blood flow is routed to collateral veins.

Sclerosing agents work best on smaller veins, spiderbursts, and when there are relatively few varicosities, but can be used on almost all varicose veins. Disadvantages include a brown discoloration of skin that may not fade. Some physicians consider sclerotherapy to be of little value because the results are not permanent. Also, the success of corrective surgery will be decreased if sclerotherapy has been tried and failed.

Surgical therapy involves extensive ligation and stripping of the greater and lesser saphenous veins. Surgery is reserved ideally for patients who are extremely symptomatic, those who suffer recurrent superficial vein thrombosis, and/or persons who develop skin ulceration. Surgery may be indicated solely for cosmetic reasons. Patients recover quickly and resume normal activities.

Nonpharmacologic treatment includes the use of elastic compression stockings to enhance the skeletal muscle pump and counterbalance the hydrostatic pressure within the veins. Clinical trials have been conducted to compare patients with varicosed veins who wore graduated elastic compression hosiery versus others who did not. The results demonstrated

Table 2
Representative Uses for Elastic Support Hosiery

Moderate Compression:
- mild varicosities
- mild aching legs
- mild swelling after cast removal
- mild swelling of the ankles from extended periods of standing

Firm Compression:
- painful varicosities
- chronic aching legs
- pronounced swelling after cast removal
- chronic swelling of the ankles from extended periods of standing
- prophylaxis against possible clotting after vein stripping
- mild, reversible lymphedema
- mild thrombophlebitis

Heavy Compression:
- severe, painful varicosities
- severe swelling after cast removal
- pronounced swelling of the ankles due to poor circulation
- prophylaxis against anticipated clotting after vein stripping
- chronic venous insufficiency
- severe, reversible lymphedema
- severe thrombophlebitis

that venous elasticity is greater in persons who wore the stockings for 4 to 6 weeks than in those who did not.

Elastic support hosiery is sometimes the only treatment advisable for patients who are too ill or too elderly to tolerate other forms of therapy. They are particularly valuable for persons whose activities involve long periods of standing or heavy lifting and for pregnant women.

Medium to heavy-weight elastic hosiery support veins in the feet and legs. Those that fit up to, but not over the knee, are the best nonoperative approach to managing varicose veins. Reasonably good control can be maintained when these are worn during extreme physical stress. It should be assured that the stockings provide a tight fit, but are neither too loose, nor too binding.

Frequent periods of rest with elevation of the limbs are indicated. Symptoms often decrease when the legs are elevated periodically, when prolonged standing is avoided, and when elastic support hosiery are worn. Tightly-fitting undergarments such as girdles should be avoided. High boots can impede circulation in the legs.

If stasis ulcers are present (typically in the region of the ankle), warm, moist dressings can be applied locally. If infection develops, topical and/or systemic antibiotics may be administered. If extensive fibrosis develops, it may be necessary to excise the entire area. Skin grafting may be required to reduce the chance of ulceration.

Patient Advice

While there are numerous types of elastic stockings sold commercially, truly therapeutic support hosiery must create pressure on the legs in a "graded" manner. This means that they must produce the greatest compression at the ankles, with a gradually reducing amount along the length of the leg.

To provide medically beneficial support, the graded compression must facilitate blood flow up the leg toward the heart. Properly fitted support hosiery compresses surface veins, thus forcing blood into the deeper veins accelerating upward blood flow.

Elastic support hosiery are made from spandex and high quality nylon to prepare fashionably acceptable products ranging in sizes small, medium, large and extra large. They are available as below the knee, above the knee, full-length and panty hose styles, and in moderate, firm and high compressions. There are slight variations in the compression depending on the manufacturer, but the prevalent ranges are based on compression at the ankles. Moderate compression refers to 10-25 mm Hg, heavy relates to 25-50 mg Hg, and firm spans the top and lower compressions of each respectively. Representative uses for each of these categories of compression are presented in Table 2.

Table 3
Patient Advice for Persons with Varicose Veins

- Elevate feet whenever possible.
- Avoid prolonged periods of sitting or standing, which causes blood to accumulate in the lower legs and causes ankles and veins to swell.
- When sitting, do not cross your knees or ankles.
- On long trips, walk up and down the aisles of the plane or train periodically, or stop the car to stretch your legs. If elastic stockings have been prescribed, be sure to wear them while traveling.
- Walk, run or swim regularly to strengthen leg muscles.
- Avoid constricting clothing. Tight garters, girdles, panty hose, and high boots can impede the circulation in the legs.
- Avoid heavy lifting.
- If necessary, lose weight.

When fitting elastic support hosiery, most manufacturers suggest taking two measurements: calf circumference and leg length. Calf circumference should be determined at its largest measurement. Leg length is usually measured from the heel at the floor to the bend in the knee. Panty hose sizes are based on the patient's weight and height using the chart supplied by the manufacturer.

High compression hosiery requires more circumferential measurements — ankle, calf, mid-thigh and upper-thigh, depending on the style of hosiery the patient desires.

Other patient information is included in Table 3.

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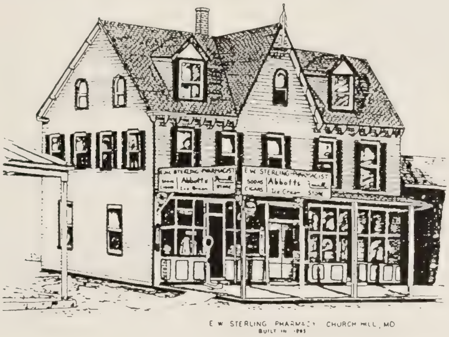
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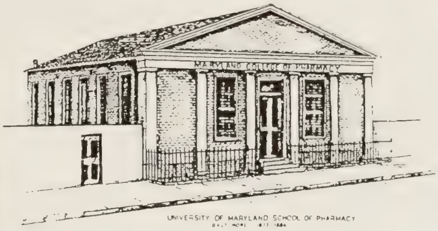
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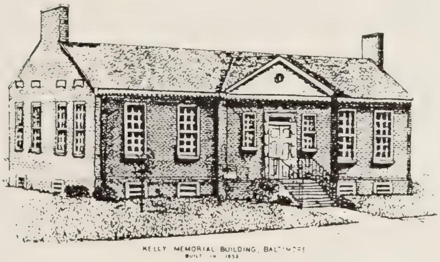
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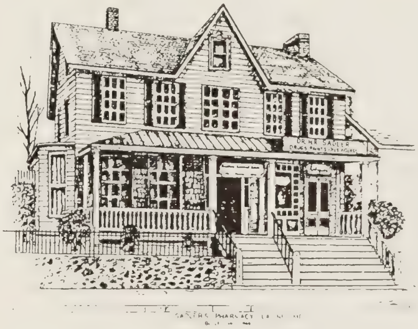
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Myths & Misconceptions About Saving for College

We send our kids to college to prepare them to face the world. But long before we help them pack, we need to prepare financially. That means shedding some of the misconceptions about paying for college. Here's a sampling.

Myth #1: "Always follow a conservative path with your kid's college funds." To gain ground on today's 6 to 7 percent annual tuition increases, you may need to grow the funds more aggressively, enjoying the benefits of long-term compounding. Shift to more conservative investments as college approaches.

Myth #2: "Saving now hurts your financial aid chances later." True, financial aid tends to go to those showing the most need -- or the fewest assets. However, some investments, such as cash-value life insurance or annuities, may not count as assets when determining eligibility.

Myth #3: "Put college funds in your kids' names to reduce your asset base." True, the investments will have to be in someone's name, and current tax laws do allow each parent to transfer $10,000 annually to each child with no gift-tax implications. But financial aid decision makers will consider 35 percent of your child's assets "available" to pay for college, compared to just 5.6 percent of yours.

Myth #4: "Smart kids earn scholarships - and great campus jobs." Full-ride scholarships are few and far between. And at many colleges, scholarship money can limit eligibility for other grant or work opportunities. A campus job will cover some expenses, but it may fall short of paying for tuition, room and board.

Myth #5: "You'll cover college costs with current compensation." Typically, family savings account for 61 percent of college financing, and although your salary may increase annually, so does tuition. Based on current trends, you could pay as much as $126,000 to send today's newborns through a state university in another 18 years -- or even a quarter of a million dollars at a private college!

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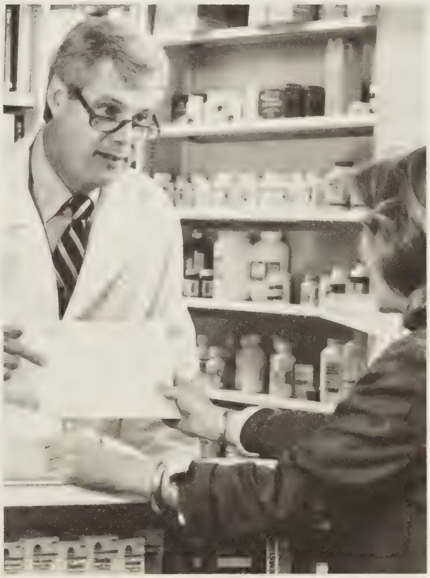

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Continuing Education Quiz

January / February 1997

This month's questions are taken from the article on Patient Counseling on Varicose Veins. Circle your answers to the following questions and mail the entire page to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members $ 5.00). The completed quiz for this issue must be received by March 15, 1999. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly. ACPE# 129-144-96-003-H01

Name ______________________________

Address ______________________________

City/State/Zip Code ______________________________

1. The deep veins of the venous system are located, to the greatest extent, in the:
   a. bones.
   b. connective tissue.
   c. muscle mass.
   d. skin.

2. Which of the following is LEAST likely to occur when a person is standing perfectly still?
   a. Blood volume diminishes
   b. Fluid will leak into the tissue spaces
   c. Blood collects in the lower extremities
   d. Venous pressure drops in the lower part of the leg

3. Varicose veins classed as primary are MOST likely to result from:
   a. deep venous insufficiency.
   b. incompetent perforating veins.
   c. deep venous occlusion.
   d. incompetent superficial veins.

4. Hydrostatic pressure, to the greatest degree, results from:
   a. the density of the atmosphere.
   b. centrifugal force.
   c. the resistance against the flow of blood.
   d. the weight of water.

5. When veins have been stretched by excessive venous pressure for a prolonged period of time, which of the following is most likely to occur?
   a. The diameter of both the veins and their valves increases.
   b. The diameter of the veins increases but not that of their valves.
   c. The diameter of the valves increases but not that of the veins.
   d. The diameter of neither the veins nor their valves increases.

6. Drugs used to treat varicose veins are referred to as:
   a. thrombolytic agents.
   b. anticoagulants.
   c. sclerosing agents.
   d. varicocele agents.

7. When a person stands upright, the pressure in the right atrium is approximately:
   a. 0 mm Hg.
   b. 60 mm Hg.
   c. 90 mm Hg.
   d. 120 mm Hg.

8. All of the following are attributes of varicose veins EXCEPT:
   a. abnormal constriction.
   b. elongated areas.
   c. prominence.
   d. tortuous.

9. To provide medically beneficial support, properly fitted elastic hosiery must produce the greatest compression at the:
   a. toes.
   b. ankles.
   c. calves.
   d. knees.

10. Hydrostatic pressure along the length of the leg:
   a. decreases proportionally with the distance from the foot to the heart.
   b. increases proportionally with the distance from the foot to the heart.

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Call for APhA - Delegates - Maryland is entitled to 7 delegates at the 1997 APhA Convention, which will be held in Los Angeles from March 8 -12, 1997. In addition, we are permitted to appoint 5 alternate delegates. Each delegate must be an active member of APhA. Any interested person should contact the MPhA office at (410) 727-0746 or (800) 833-7587 for a Delegate Credential Certificate.

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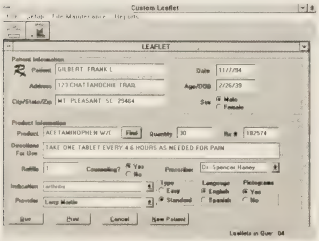

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Date: 11/7/94
Age/DOB: 2/26/39
Sex: ● Male ○ Female
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Quantity: 30
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Refills: 1
Counseling? ● Yes ○ No
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MARYLAND Pharmacist

Volume 73, No. 2

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- ***STUDENT ARTICLE:***

  The Pros and Cons of Thalidomide Therapy

- ***POISON CENTER UPDATE***

- ***PRESIDENT'S COLUMN***

- ***RECOGNIZING EXCELLENCE:***

  MPhA Awards Nominations

1997 MPhA Elections

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March / April 1997

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President's Commentary

1997 Elections

Ernest Testerman, P.D., President

One of the most important responsibilities we have as citizens of the United States is electing our future leaders. They are our voice in guiding our country. In pharmacy, our responsibility is the same, in order to assure strong leadership of our professional organizations.

I believe that the slate of candidates for the 1997 Maryland Pharmacists Association leadership elections are some of the best pharmacy leaders in Maryland today. We have broad geographical representation as well as a diverse group of practitioners -- some come from independent pharmacies, some from chain pharmacies, some from managed care, and some from consultant pharmacy settings. The different perspectives each of these candidates brings to the MPhA helps make us a stronger association.

According to the Maryland Pharmacists Association Bylaws:

A mail ballot will be submitted to the active membership by mail within sixty days after the nominations have been approved by the House of Delegates. The officers and trustees will be elected from the persons whose names are printed on said official ballots; the nominees for each position receiving the highest vote, as certified by the Canvassing Committee, will be declared duly elected. In the event of a tie vote, a supplemental mail ballot election will be held.

The candidates for MPhA's 1997 elections were approved by the Board of Trustees at the Thursday, January 23, 1997 meeting. The MPhA House of Delegates approved the slate at its most recent meeting during the annual MPhA Mid-Year Educational Seminar held on Sunday, February 23, 1997 at Loews Annapolis Hotel.

I cannot emphasize enough . . . **Your Vote Counts!** Some of the officers and trustees elected with the past few years have come down to a difference of only a few votes.

Review the statements of the candidates located on pages 10 - 17. Cast your vote by checking the appropriate box next to the name of the candidate you feel would best serve your interests and the interests of the Association; the ballot is on page 23. Once you have finished voting, fold your ballot with the return address facing out, add a stamp, and mail your vote to the MPhA offices **postmarked by Saturday, May 3, 1997.**

The elected officers and trustees will be installed at the 115th Annual Maryland Pharmacists Association Convention, June 15-18, 1997 in Ocean City, Maryland. The names of the elected officers and trustees will appear in the June 1997 MPhA Newsletter.

Thank you for doing your part for the Association.

Anticonvulsant Therapy For Pregnant Patients

Cindy Denemark, R.Ph.
EDS, Pharmacist Consultant

Women who have epilepsy have a higher risk of having children with birth defects than the general population. We do not know whether the problems are related to the drugs used to treat the disease, the disease itself or perhaps a genetic connection.

The practitioner must examine the current status of the disease. Have there been recent seizures? Is there a risk for status epilepticus? Might therapy be withdrawn during the pregnancy? Some medications have less risk than others and it might be advisable to change the course of therapy.

Table One lists the most common anticonvulsants and the FDA rating as to the risk involved in treating pregnant women with the drug. Severity 'D' is defined as positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans. Potential benefits may warrant use of the drug in pregnant women despite the potential risk. Severity 'C' is based on animal reproductive studies. No adequate human studies have been done. Potential benefit may again warrant use of the drug in pregnant women despite the risk.

The majority of the medications pose a high risk to the fetus and to the mother. Clonazepam and primidone have not been rated by the FDA. The risk involved in using these two medications is minimal.

The challenge for the pharmacist is to help both the physician and the patient make the most informed judgement on the treatment regimen for epilepsy during the gestation period. The long reaching effect of the actions taken can make a difference.

Table One

FDA CATEGORY	MEDICATION	PROBLEMS - (condensed listing)
D	PHENYTOIN	Fetal hydantoin syndrome, including cleft palate, malformed ears, urogenital malformations and skeletal abnormalities.
C	LAMOTRIGINE	Studies have not been done in humans.
D	VALPROIC ACID	Teratogenic effects including encephaly, low meningomyelocele and spina bifida.
C	CARBAMAZEPINE	Small head circumferences, low birth weight, cranofacial defects, fingernail hypoplasia, developmental delays and spina bifida
C	GABAPENTIN	Studies have not been done in humans.
C	FELBAMATE	Studies have not been done in humans.
Not Rated	PRIMIDONE	Symptoms similar to fetal hydantoin syndrome have been shown to occur with use.
Not Rated	ETHOSUXIMIDE	Problems in humans have not been documented
D	PHENOBARBITAL	Readily crosses the placenta. Accumulates in fetal liver and brain, although detected throughout the body. Increased incidence of brain tumors.

Recognizing Pharmacy Excellence

The 1997 MPhA Awards

Each year, the Maryland Pharmacists Association recognizes professional excellence through a series of awards. To nominate a pharmacist for one of the awards described below, complete the official Award Nomination Form. The Award Nomination Form information should be clear and legible. The forms should be sent to: **Award Nominations**, c/o Maryland Pharmacists Association, 650 West Lombard Street, Baltimore, Maryland 21201-1572.

All nominations will be reviewed by the Past Presidents Council who is responsible for selecting the award recipients. The decision of the Council is final. Award recipients will be notified in advance of the Annual Awards Banquet at the 115th Annual MPhA Convention.

For consideration, all nominations must be received no later than April 30, 1997.

- **Hoechst Marion Roussel Distinguished Young Pharmacist Award** - Awarded to a pharmacist who has graduated within the past ten years and who has made a significant contribution to the profession through service to a local, state or national pharmacy organization. ***Who is Eligible:*** Any MPhA pharmacist member who graduated from pharmacy school in 1988 or after.

- **Maryland Pharmacists Association Honorary President** - An honorary position on the Board of Trustees given to a person, not necessarily a pharmacist or member of MPhA, who has worked for the MPhA or Maryland Pharmacy over a long period of time. ***Who is Eligible:*** Any long standing contributor to the profession or the Association.

- **Seidman Distinguished Achievement Award** - Created to honor the major impact on the pharmacy profession made by Henry Seidman, this award is presented for outstanding service by a Maryland pharmacist to the pharmacy profession during *either* the past year or over a period of years. ***Who is Eligible:*** Any MPhA pharmacist member who meets the criteria of the award.

- **Wyeth-Ayerst Bowl of Hygeia Award** - The Bowl of Hygeia recognizes a pharmacist who has performed outstanding services to the community in any area, with a particular emphasis on non-pharmacy contributions. ***Who is Eligible:*** Any MPhA member pharmacist who has not already received the Bowl of Hygeia.

- **Dupont Innovative Practice Award** - Established in 1993, this award aims to recognize forward-thinking pharmacists who have expanded their practices into new areas. This may include adding a new service, restructuring a pharmacy and its current services, or developing a completely new practice. ***Who is Eligible***: Any MPhA pharmacist member who meets the criteria of the award.

Maryland Pharmacists Association
Award Nomination Form

To nominate a Maryland pharmacist for one of MPhA's annual "Recognizing Pharmacy Excellence" awards, this form must be completed and returned to the Maryland Pharmacists Association no later than April 30, 1997. All nominations will be held in strictest confidence by the MPhA Past Presidents Council, which is responsible for selecting the award recipients. The decision of the Council is final. Award recipients will be notified in advance of the presentation of the award.

Please consider the following nominee for:

☐ ***Hoechst Marion Roussell Distinguished Young Pharmacist Award***

Nominee____________________
Home Address____________________
City/State/Zip____________________
Current Place of Employment/Practice
____
Telephone ____________________
Work Telephone ____________________
Name of Nominator____________________
Nominator's Telephone____________________

☐ ***Seidman Distinguished Achievement Award***

Nominee____________________
Home Address____________________
City/State/Zip____________________
Current Place of Employment/Practice
____
Telephone ____________________
Work Telephone ____________________
Name of Nominator____________________
Nominator's Telephone____________________

☐ ***Dupont Innovative Practice Award***

Nominee____________________
Home Address____________________
City/State/Zip____________________
Current Place of Employment/Practice
____
Telephone ____________________
Work Telephone ____________________
Name of Nominator____________________
Nominator's Telephone____________________

☐ ***Wyeth-Ayerst Bowl of Hygeia***

Nominee____________________
Home Address____________________
City/State/Zip____________________
Current Place of Employment/Practice
____
Telephone ____________________
Work Telephone ____________________
Name of Nominator____________________
Nominator's Telephone____________________

☐ ***MPhA Honorary President***

Nominee____________________
Home Address____________________
City/State/Zip____________________
Current Place of Employment/Practice
____
Telephone ____________________
Work Telephone ____________________
Name of Nominator____________________
Nominator's Telephone____________________

Attach a current resume or curriculum vitae for the nominee that shows their professional and personal achievements. This information is essential for the Past Presidents Council to make its decisions as to which candidates will be recipients of the "Recognizing Pharmacy Excellence" awards. In addition, the nominator should attach a brief letter explaining why the nominee is worthy of receiving this award.

Return the completed form to:
Award Nominations, c/o Maryland Pharmacists
Association, 650 West Lombard Street,
Baltimore, MD 21201-1572

Fold Line

Award Nominations
c/o Maryland Pharmacists Association
650 West Lombard Street
Baltimore, Maryland 21201- 1572

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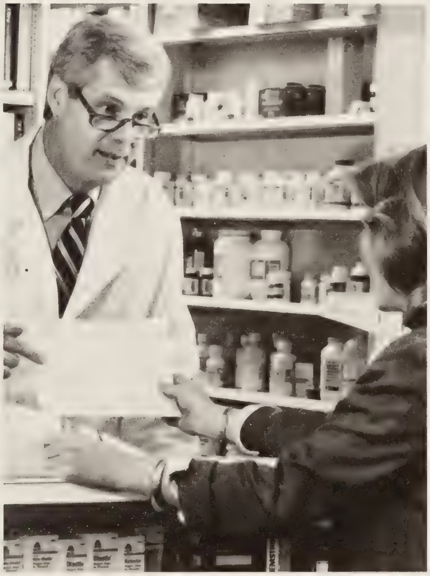

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Statements of the Candidates

Maryland Pharmacists Association 1997 Elections

Candidates for President-Elect

Alisa Billington, P.D.
48 Loveton Farms Court
Sparks, Maryland 21152

University of Maryland School of Pharmacy
Graduation Year: 1991
Practice: Long Term Care
Employer: NeighborCare Pharmacy

If elected to this position, I will work for the goals common to all pharmacists. My background includes independent and chain community pharmacies as well as dispensing and consulting for a long term care organization. Our association has recently undergone many changes and needs to continue to evolve to better serve the needs of our members. As pharmacists, we are constantly changing with the times to maintain our position as front-line caregivers.

I will work hard to assure that pharmacists continue to be leaders in the provision of the expertise and knowledge that our patients have come to expect while getting paid for the value that we provide.

Gerard Herpel, P.D.
2224 Accident/Friendsville Road
Accident, Maryland 21520

University of Maryland School of Pharmacy
Graduation Year: 1982
Practice: Independent Pharmacy Owner
Employer: Deep Creek/EPIC Pharmacy

If elected to this position, I will strive to keep MPhA in the forefront of pharmacy issues in the state of Maryland.

As pharmacists in these changing times, we will need a strong state association to work with Annapolis and the Maryland Board of Pharmacy to protect our profession in the next millennium.

It will be an honor if elected by my peers to serve as President-Elect for the upcoming year.

Statements of the Candidates

Maryland Pharmacists Association 1997 Elections

Candidate for Vice-President

Richard Baylis, P.D.
1700 Sherwood Avenue
Baltimore, Maryland 21239

Union University Albany College of Pharmacy
Graduation Year: 1961
Practice: Consultant Pharmacist
Employer: Howard and Morris Institutional Pharmacy

I am greatly honored to be nominated for vice-president of the Maryland Pharmacists Association. If elected to this position, I will strive to ensure that the Maryland Pharmacists Association continues to be the premier state professional society in the U.S. Our association must continue to encompass all aspects of our profession. It must represent us as medical professionals, as well as protect our business interests.

The Association faces many challenges, some new and some old. Managed care, private and public, is the current main challenge. The Association must provide its members with information and education about this form of health care. We must be willing to participate in educating the health care managers as to what the pharmacy profession is all about. We need an aggressive approach in steering the managers of health care to our point of view.

The second challenge is the new Pharmacy Practice Act. We must continue to work with the Board of Pharmacy to guide these bills through the legislature. Once passed, we need to provide the educational platform for its implementation.

The third challenge is the status of our building. This problem is in the hands of our legal counsel and the Building and Property Committee. The Association Board will make the final decision as to what move to make when presented with solutions by the committee.

The fourth challenge is robotics and the total change in our daily routine as pharmacists. The automation of the dispensing of medications means a drastic change in how we practice pharmacy. Are we ready for this? Can we stop counting pills and survive both professionally and financially? Should we allow the manufacturer to take over the dispensing role and leave clinical aspects to us? These are issues that need to be discussed in open forums.

I have had many years of experience in Association affairs, having worked in its offices for more than five years while serving as DUR Director. I am currently a member of the Legislative and Building and Property Committees. I am also the Chairman of the Annual Regional Seminar and a Board member of the Maryland Chapter of the American Society of Consultant Pharmacists.

Statements of the Candidates

Maryland Pharmacists Association 1997 Elections

Candidate for Vice-President

Joseph Marrocco, P.D.
3909 Eland Road
Phoenix, Maryland 21131

Duquesne University School of Pharmacy
Graduation Year: 1973
Practice: Pharmacy Development Manager
Employer: Rite-Aid Pharmacies

If elected to this position of Vice-President, I will devote my focus and energy to enable MPhA to "CHART" the course, not merely follow it, as changes continue to impact our pharmacy profession.

Presently serving as your elected Trustee of MPhA, I present to you my near perfect meeting attendance, work with the yearly terms of five diligent, dedicated presidents of your fine state association, whom like I, volunteer their time to keep our association at the forefront of pharmacy matters where/whenever applicable.

I have been honored to serve you and MPhA two prior terms as Vice-Speaker and Speaker of the House of Delegates. These positions enabled MPhA to "team" on a number of important issues that reflect us all.

Presently, I also serve as Chairman of the Building and Property Committee, a responsibility I have accepted for the past several years. The focus of my energy in this committee is immediate and urgent, as we are in the midst of information gathering and discussion with our legal counsel, committee members, and the Board to determine and finalize what location and building structure at the University of Maryland Medical System and Professional Schools campus would best serve our MPhA members for the present and also the years to come.

As a Pharmacy Development Manager, I recognize and share your concerns of third parties, prescription benefit managers, and drug manufacturers. My goal, like yours, is to continue to strive to have pharmacists compensated for our knowledge. Continued widespread efforts and recognition for our "cognitive services" is paramount in my sphere of thinking.

In final analysis, I pledge to you, my fellow pharmacists of all spheres of practice, an open-door policy that is reflective and responsive to your concerns in your daily practice setting. I would welcome routinely your feedback and ideas of where our association should be pointing, and the course it should be "charting".

As your elected leader, I feel this mission is paramount and vital to us all. Thank you for your consideration and support. I would be honored to serve you, and our most trusted profession of pharmacy.

Statements of the Candidates

Maryland Pharmacists Association 1997 Elections

Candidates for Treasurer

Lance Berkowitz, P.D.
3801 Canterbury Road #802
Baltimore, Maryland 21218

Medical College of Virginia School of Pharmacy
Graduation Year: 1965
Practice: Chain Pharmacy
Employer: Arcade/HMI Pharmacy

If elected to this position, I will make the time and effort to provide the MPhA with guidance and leadership acquired through thirty years of pharmaceutical practice, in a multitude of care settings.

Having served as treasurer of two large condominium associations, the treasurer of EPIC Pharmacies, one of the largest independent pharmacy chains in the country, as well as operating two very profitable community pharmacies, I have demonstrated the ability to handle responsibility effectively and efficiently and secure successful conclusions for difficult issues.

The dynamics of a rapidly changing health care environment dictate the need for the strongest, most experienced association leadership, and I will bring these capabilities to the MPhA if elected to office.

Alfred Schwartzman, P.D.
27 Chasemount Circle
Baltimore, Maryland 21209

University of Maryland School of Pharmacy
Graduation Year: 1959
Practice: Independent Pharmacy Owner
Employer: A & B Drugs/EPIC Pharmacy

If elected to this position of Treasurer, I will use my experience of 40 years as an independent pharmacist in fiscal responsibilities and restraint. Currently, I am treasurer of the Baltimore Metropolitan Pharmacists Association, as I have been for the past five years.

Statements of the Candidates

Maryland Pharmacists Association 1997 Elections

Candidates for Trustee Seat #1

Frank "Butch" Henderson, P.D.
3982 Old Federal Hill Road
Jarrettsville, Maryland 21084

University of Maryland School of Pharmacy
Graduation Year: 1988
Practice: Chain Pharmacy
Employer: Klein's Pharmacy

If elected to this position, I will look forward to supporting the efforts of the Association. I am both interested and concerned with the redefining of pharmacy practice today and how that will impact each of us. As the Director of Pharmacy Operations for a small (five store) chain, I divide my time between pharmacist/manager/director. This keeps me in touch with the issues of concern to all levels of retail practice, and as one who recognizes what a valuable resource the Association is to each of us, I look forward to doing what I can to serve and support

Matthew Shimoda, Pharm.D., FASCP
1079 Huntfield Road
Westminister, Maryland 21157

University of Maryland School of Pharmacy
Graduation Year: 1984
Practice: Independent/CLIA Lab
Employer: Co-Owner Health Care Professionals

If elected to this position, my vision of pharmacy is that we as a profession *must* go forward with pharmaceutical care and be aware of the changes that are paramount to our profession.

I believe that our practice in pharmaceutical care will continue to grow given the correct direction.

I believe my role as a trustee will bring forth to this organization direction that will lead us into the 21st century.

Statements of the Candidates

Maryland Pharmacists Association 1997 Elections

Candidate for Trustee Seat #2

Rhea-Marie del Rosario, P.D.
1203 Sabina Avenue
Baltimore, Maryland 21209

University of Maryland School of Pharmacy
Graduation Year: 1995
Practice: Independent
Employer: Horizons/EPIC Pharmacy

If elected to this position, I will enthusiastically strive to improve the profession of pharmacy by representing the needs and desires of its members to the best of my ability.

Without change, there is no progress. I would like to be an instrumental part in making these changes in a positive direction.

Paul R. Holly
9012 Scotts Haven Drive
Baltimore, MD 21234

West Virginia University
Graduation Year: 1970
Practice: Independent
Employer: Tuxedo Pharmacy

If elected to this position, I will serve the pharmacists of this state, and the profession of pharmacy with the same excitement and dedication that I serve my patients. I think fondly of how pharmacy was in the past, and anticipate with excitement and vigor how pharmacy will be in the 21st Century. It would be an honor to be elected to this position. I look forward to working with "our" associaiton in promoting "our" profession. Thank you for your support.

Statements of the Candidates

Maryland Pharmacists Association 1997 Elections

Candidates for Trustee Seat #3

Leo Mallard, P.D.
4750 Camp Roosevelt Drive
Chesapeake Beach, Maryland 20732

Northeastern University College of Pharmacy
Graduation Year: 1969
Practice: Independent Pharmacy Owner
Employer: Care Drug-Calvert/Arundel Pharmacy

If elected to this position, I will continue to use my varied experience in health systems, hospice care and networking of community pharmacies in service to our profession. As healthcare moves toward system integration, pharmacists from all practice settings will capitalize on the spectrum of our knowledge. We will collaborate with other health care professionals in improving patient care, delivering efficiencies, and improving outcomes. I respectfully ask for your vote.

Michael Souranis, P.D.
622 Rappolla Street
Baltimore, Maryland 21224

University of Maryland School of Pharmacy
Graduation Year: 1990
Practice: Independent Pharmacy Owner
Employer: Bayview/EPIC Pharmacy

If elected to this position, I will help position our association to focus on the challenges that our profession faces, where all efforts past and present can foster our growth and encourage new ideas that are needed to direct the future of pharmacy. Through our committees, we can define our stance and help shape agendas to bring about positive outcomes to benefit pharmacists through the state.

Statements of the Candidates

Maryland Pharmacists Association 1997 Elections

Candidates for Trustee Seat #4

Crystal King, P.D., M.G. A.
14805 Windmill Terrace
Silver Spring, Maryland 20905

University of Maryland School of Pharmacy
Graduation Year: 1981
Practice: Community Hospital
Employer: Montgomery General
Community Pharmacy

If elected, I will continue to consider the various issues brought before the Board by utilizing my varied practice perspectives. These include chain, independent and outpatient community settings in staff as well as management capacities. Additionally, my work with interdisciplinary teams for providing comprehensive care will further improve my capability to respect different viewpoints regarding the practice of pharmacy and its relation to other health care providers.

As the delivery system of health care continues to evolve, we will need to be careful to preserve and enhance our professional autonomy. This is one of MPhA's primary goals and one to which I am highly committed. My work with the Board of Pharmacy Task Force to revise the Practice Act demonstrates this. I will continue to press for the passage of the collaborative practice and medication administration sections which were dropped from the current bills.

I have been honored to serve the past two years as your Vice-Speaker and Speaker. I stand ready to continue working on your behalf to further our Association and the practice of pharmacy.

Abigail M. Lagman, P.D.
5115 Vest Lane
Waldorf, Maryland 20601-2214

University of Maryland School of Pharmacy
Graduation Year: 1993
Practice: In-Patient Institutional Pharmacy
Employer: University of Maryland Medical Systems

If elected to this position, I will do my best to represent the Maryland Pharmacists Association, the profession of pharmacy and you - the pharmacists of the state of Maryland.

As a Trustee, I will be in the forefront of promoting our profession. I will be your voice in the association by actively participating in meetings and committees. I have the work-ethic, dedication and leadership to help our profession make a positive impact on pharmacy and healthcare.

It would be an honor to be elected to the MPhA Board of Trustees. I look forward to working with MPhA in promoting our profession of pharmacy.

The Pros and Cons of Thalidomide Theraphy

Mary Benson
Second Year Student
UMAB School of Pharmacy
ASP President - Elect

The drug thalidomide has basically been taboo in our culture for the past thirty years. The sedative that was never approved in the United States was widely distributed in Europe until it was connected with birth defects in 1961[1,2]. Since that time, however, it has been found that thalidomide is effective in the treatment of several conditions.

The original indication of thalidomide was controlling epileptic episodes. It proved to be ineffective in that capacity, but was found to be a very good sedative[3]. It was believed to be so safe that it was given to pregnant women as an antiemetic agent[1].

In 1959, however, reports began filtering in that thalidomide could be causing birth defects[4]. Approximately 12,000 birth defects were blamed on thalidomide from 1953 to the early 1960's. The most common type of birth defect involved shortened, malformed, and/or missing arms, hands, legs, and feet. It was later determined that a woman only had to take one dose of thalidomide between days 45 and 55 of her pregnancy to significantly increase her chances of having a baby with phocomelia[5]. Because of this, the use of thalidomide was, naturally, discontinued.

That is not the end of thalidomide's story, however. The drug has been found to be useful in the treatment of several diseases some of which did not even exist when thalidomide was first put on the market.

One of the first illnesses to prompt doctors to look at thalidomide again was leprosy. Besides suppressing erythema nodosum leprosum[6], thalidomide has been successfully used to treat graft versus host disease that is sometimes associated with bone marrow transplants[7], ulcers from Behcet's disease[8], systemic lupus erythematosus[9], and as an immunosuppressant agent in preventing cardiac allograft rejection[10].

In the late 1980's, physicians began investigating the use of thalidomide as a treatment for some of the symptoms of a relatively new disease, acquired immune deficiency syndrome (AIDS). The AIDS condition that probably is treated most often with thalidomide is aphthous ulcers, which are recurrent ulcers of an unknown cause. These ulcers can appear anywhere along the digestive tract of an AIDS patient, especially in the mouth, throat, and rectal area. They often contribute to the significant weight loss that AIDS victims face[11].

A group from the Infectious Disease Unit of the Royal Brisbane Hospital conducted a study on the effectiveness of thalidomide when used to treat aphthous ulcers. Their test group consisted of 20 human immunodeficiency virus (HIV), the virus that causes AIDS, positive patients who had ulcers along the gastrointestinal tract that had not responded to any other treatments such as topical and oral steroids, antacids, H_2 receptor antagonists, and empirical antiviral therapy with acyclovir or ganciclovir. The standard treatment was 200mg of thalidomide a day for 14 days. The treatment was adjusted as needed; for example, patients with rectal ulcers had to undergo treatments for a time period that extended past two weeks. Nineteen of the 20 participants experienced "prompt abatement of symptoms or resolution of ulcers." The other patient had to terminate the treatment due to side effects before results were seen. Side effects were experienced by 35% of the patients. A rash was reported by 5 of these patients. Excessive fatigue and peripheral neuropathy were each reported by one participant[11].

Bouza and coworkers also describe favorable results from thalidomide use on two AIDS patients. One of the patients had suffered from a fever for six months. The physicians at the hospital where the man was treated added a regimen of 100mg of thalidomide a day to his list of medications. Within three days, the patient's temperature had returned to normal, and he experienced a 9kg weight gain. After treatment was stopped, the fever returned. The patient did not experience any side effects. The other patient described in the letter was admitted to the hospital for a persistent fever, asthenia, and tuberculosis. Six days after thalidomide was added to his drug therapy, his condition was given the rating of acceptable clinical status, and he was released from the hospital. After his release, he gained weight and remained in good condition[12].

Thalidomide is also exhibiting what could prove to be very promising signs in the lab. One study concluded that thalidomide reduces HIV-1 replication in promonocytic U1 cells[13]. While this was just a preliminary study, the results may open up another avenue for research into fighting this disease.

Now that we have seen the evidence of what thalidomide can do, we need to ask ourselves whether it is worth the risk of bringing the drug to the public as a possible treatment for some of the symptoms from which AIDS patients suffer or not.

I feel that we should use every resource that we have available, including thalidomide, to fight AIDS. It may not be able to prevent or cure the disease, but it does help relieve some of the patient's suffering in many cases. I do not think that distributing the drug to males who are being carefully supervised by their physicians would cause much of a problem.

The decision that would need to be considered more carefully is whether or not the drug should be given to women of child-bearing age. To restrict an entire group of people from a treatment is normally very difficult to do.

With some restrictions, it may be possible to allow some women to receive thalidomide. These restrictions would have to include some form of mandatory birth control. The method of birth control would be decided by the woman and her doctor.

Careful monitoring of the drug therapy would be necessary for all patients, both male and female. Counseling on side effects including birth defects, would also have to be stressed. Extra special attention would have to be paid to the drug supply.

Some of these precautions would have to take place to help prevent some of the abuses of thalidomide that have occurred in other countries.

Brazil seems to be the country that has had the most shocking problem due to the use of thalidomide. The drug is frequently used there for treatment of leprosy. Even though the drug is not prescribed to women of child-bearing age there, they sometimes get it from their husbands. As of July 1994, there had been reports of 46 new cases of babies born with birth defects due to the use of thalidomide during pregnancy[14].

The United Kingdom has not reported any new "thalidomide babies." They have, however, had a problem with side effects not being fully disclosed to the patient. Many patients being treated for leprosy there claim that the side effect of peripheral neuropathy was not widely impressed upon them[15].

These are some of the reasons that thalidomide must be very carefully controlled if it is to be made available for widespread use in the United States. I also feel that it is important for more studies to be done on the actions of the drug.

To exclude thalidomide from use just because it is teratogenic seems closed minded to me, especially considering drugs such as misoprostol, the German measles vaccine, and even birth-controls pills are so widely used. While these drugs may not cause birth defects to the extent that thalidomide does, they are used by a larger population than thalidomide would be used.

Thalidomide has been responsible for many tragic birth defects. While this should not be forgotten, it is time for the health care industry to take another look at this drug. The therapeutic indications are different this time. I feel that with proper monitoring, it would be a reasonable decision to add thalidomide as a possible treatment for patients suffering from symptoms of AIDS such as aphthous ulcers and prolonged fever.

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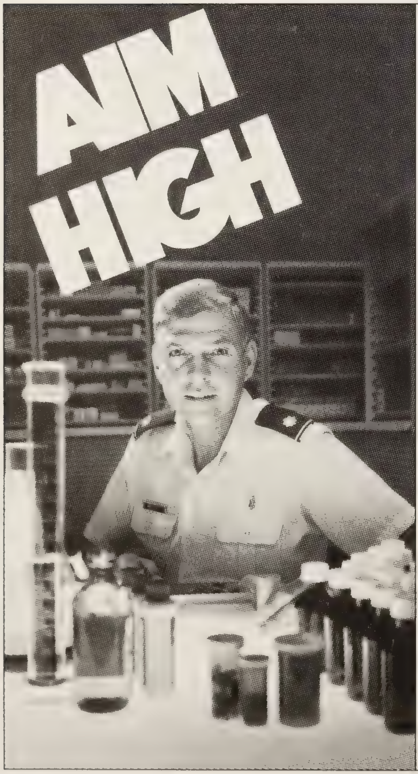

PHARMACISTS:
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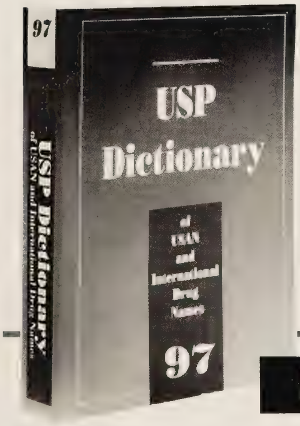
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1997 Maryland Leadership Elections
Official Ballot

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Fold Line

Interactions...

Springtime in Annapolis

David A. Knapp, Ph.D., Dean
University of Maryland School of Pharmacy

The annual 90-day session of Maryland's General Assembly is now in full swing. Pharmacy Practice Act Revisions and budget aid for a financially-starving Maryland Poison Center deserve your support. A thorough update of the Maryland Pharmacy Practice Act will be accomplished by passage of three bills now before the General Assembly. The bills are the result of over a year's effort spearheaded by the Board of Pharmacy working through a Task Force consisting of representatives of all the state's pharmacy organizations. I commend the many pharmacists and faculty members from throughout the state who have toiled without complaint on the many serious issues considered in the revisions. Briefings of pharmacy groups, other health professions, government agencies and legislators have been carried out during the fall and winter by Norene Pease, Task Force Chairman, David Russo, and Board Commisioner Dorothy Levi.

The pending legislation will broaden the scope of practice of pharmacy, provide updated definitions of practice functions and establish a peer review committee to assist the Board. The size and composition of the Board of Pharmacy will be altered as well as the manner of determining Board nominations.

A state's Pharmacy Practice Act sets the parameters within which the profession can function. It has been 75 years since Maryland's has been comprehensively updated! Maryland citizens spend more than $1 billion a year on prescription drugs and, unfortunately, even more than that on correcting misadventures with medicines. Pharmacy is the health profession best positioned to manage drug therapy. A revised Practice Act will help make this possible. Make sure your senator and delegates know that you want these revisions passed.

Maryland Poison Center

After three years, two statewide commissions studying the matter, and countless hours working on the problem, the Maryland Poison Center is still trying to provide poison control services to all corners of this state with a grossly inadequate budget.

The Maryland Poison Center offers 24-hour, 7-day a week telephone response to emergency poisoning requests via an 800 number. The MPC is staffed by certified poison control specialists who are pharmacists and nurses. The MPC is housed in Pharmacy Hall and receives over half of its budget from the School of Pharmacy. This was adequate when the Poison Center was founded in 1972, but since that time the call volume has mushroomed to 40,000 calls a year. Serious cases require multiple calls to paramedics, emergency rooms, physicians and hospitals. An elaborate communications network and a tie-in to the vast reference resources of the National Library of Medicine make the poison center unparalleled in its ability to deal with poisoning emergencies.

Every case that can be successfully treated at home over the telephone saves a trip to a physician or an ambulance visit to an emergency room. For every dollar spent on poison center services, seven dollars are avoided in other health care costs. It seems obvious that supporting the Poison Center should be a "no-brainer!". Well, it is! At least, apparently, if someone else pays the bills.

Two statewide studies have confirmed that the MPC requires a budget of $1.4 million a year to do its job right. The School of Pharmacy provides $636,000 and for the last three years, the Department of Health and Mental Hygiene has provided $290,000. But MPC continues to run $474,000 short of its requirements.

This session, Speaker Casper Taylor has pledged to fix the problem. Governor Glendening has been requested to put $474,000 in his supplemental budget for the Maryland Poison Center. You can help by calling or writing the Governor and members of the General Assembly in support of this request. Remember, the most frequent customer of poison center services are pre-schoolers. Your call to a legislator today may make sure that a call to the Maryland Poison Center tomorrow is answered on the first ring.

The State Capital Budget

As a state-assisted pharmacy school, we depend upon public funds for our facilities. Because of the school's rapid growth, those facilities are now far from ideal. Pharmacy Hall, which many of us still refer as the "new" pharmacy building, is almost 15 years old. It was too small to accommodate all of pharmacy's programs when it opened and it accommodates only about half now. Our faculty are spread out among three buildings on campus and a large contingent will move into the top floor of 100 N. Greene Street within the next few weeks. Laboratory research space is in particularly short supply given the success of our faculty in attracting external research funding.

Help is on the horizon. Planning money for two buildings that will help the School of Pharmacy appears in the Governor's 5-Year Capital Plan (the final year, I might add). Funds are included for the Pharmacy Hall addition, a planned eight-story building to go up in the parking lot north of Pharmacy Hall and to be connected to the older building. The addition will provide much-needed teaching space for small group work and computer-based laboratories. It will also enable us to bring together the Department of Pharmacy Practice and Science, whose faculty members are scattered across the campus.

The Health Sciences Facility II is an interdisciplinary biomedical research building that will extend the current Health Sciences Facility southward to Lombard Street. Pharmacy will occupy about 40% of the space in this building with the remainder being shared between the School of Medicine and the School of Dentistry.

These two new buildings will not help us at all until the year 2004 at the earliest. Therefore, we continue to work to convince capital budget planners to move these projects earlier in the schedule.

The General Assembly is an elected body that is responsive to all of us. Know your representatives, talk to them about issues that you care about and help make the General Assembly responsive to pharmacy's needs!

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The Maryland Poison Center

Bruce Anderson, Pharm.D., A.B.A.T.
Director of Operations

What would you do if your child swallowed a mouthful of bleach?

What would you do if you were accidently sprayed with a pesticide?

Where does the emergency room turn when someone presents with a snake bite?

The answer: *The Maryland Poison Center.*

Open 24 hours a day, seven days a week, the Maryland Poison Center is staffed by pharmacists and nurses who are experts in clinical toxicology. This free service is available by calling 410-706-7701 in the Baltimore Metropolitan area or 1-800-492-2414 from anywhere in the state.

Why have a poison center?

The Maryland Poison Center saves lives and saves dollars. It saves lives by providing emergency triage and treatment information to the general public and to health care providers. The Maryland Poison Center saves dollars through treatment strategies that allow 70-80% of all poisoning and overdose cases to be managed *safely* and *inexpensively* at home. Management at home not only saves the cost and confusion of emergency department or clinic treatment, but also decreases the use of other limited and expensive emergency health care resources (e.g., 911 ambulance transport). Estimates of the cost effectiveness of poison centers have shown **savings of $7.75 for each dollar spent on poison center services.**

This life saving and dollar saving service is extremely efficient and is quite a bargain: the cost per resident for full funding of poison center services is only **35 cents per year.**

Facts & Figures:

Since its inception at the University of Maryland at Baltimore School of Pharmacy 25 years ago, the service has grown dramatically. In 1972, the annual call volume was around 5,500 cases per year. In 1996, the Maryland Poison Center received almost 40,000 poisoning or overdose cases. The growth in funding has not kept pace with the growth in service.

Despite the widespread use of this service, a large number of Marylanders are still under served. Based upon Maryland's population and national poison center data, the total number poisonings or overdoses occurring in the state is 60,000 to 80,000 per year. This means that **twenty thousand to forty thousand** Marylanders are not calling the Maryland Poison Center and are using other, more expensive health care services.

Why don't those people call the Maryland Poison Center?

In a word: FUNDING. Without adequate funding to provide education and outreach, people do not know this service is available. Without statewide prevention and education efforts, people may not know how to poison-proof their homes. The result is additional poisonings and additional unnecessary health care costs.

Funding:

The funding challenges facing the Maryland Poison Center are not new but are becoming more acute. Over the past several years, two special statewide study groups and an assortment of university, state, and legislative analysts have poured over the books of the poison center, visited the operation, explored alternatives, encouraged collaborations, and studied funding options nationwide. The Maryland Poison Center has benefitted from the advice it has received, has become more efficient, and collaborates more than ever with its neighboring poison centers. However, the funding challenges persist. The Maryland Poison Center receives support from the University of Maryland at Baltimore School of Pharmacy and the Department of Health and Mental Hygiene. The estimated budget in fiscal year for fiscal year 1998 is $1,400,000. The Center is currently facing a shortfall of $474,000.

Impact of full, stable funding:

Three important outcomes will result from stable funding:
Better awareness of poison center services;
Higher utilization of those services;
Cost effective, appropriate management of poisoning and overdose cases.

The next step:

The challenge is to increase awareness of poison center services in Maryland and identify stable funding sources for poison center services. With your help, we can ensure that Maryland's poisoned patients and health care providers have access to this vital health care resource now and for the future.

National Poison Prevention Week

What can pharmacists do to promote poison prevention and poison center services?

National Poison Prevention Week (NPPW) is March 16-22, 1997 and is an ideal time to promote poison prevention. The basic theme for NPPW is "Children Act Fast....So Do Poisons!". But remember... poisonings don't just occur during NPPW. Every week is poison prevention week! There are numerous activities that pharmacists can participate in during NPPW and year-round to educate patients and communities about poisonings:

Distribute poison prevention information, telephone stickers and Mr. Yuk stickers.

- Conduct poison prevention programs in schools and for community groups.
- Set up a display or bulletin board on poison prevention, poisonous plants, medicines that look like candy, or Mr. Yuk.
- Give away bottles of Syrup of Ipecac or coupons for ipecac.
- Advertise in your local newspaper and include a poison prevention message.
- Collect and discard expired medications. Offer coupons or rebates in return.
- Organize a poison prevention poster contest in a local school.

Call the Maryland Poison Center to obtain poison prevention education materials or for more information: (410) 706-7604.

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Continuing Education for Pharmacists

Volume XIV, No. 8

Patient Counseling on Treatment of Vaginal Yeast Infections

Thomas A. Gossel, R.Ph., Ph.D.
Dean, and Professor of Pharmacology and Toxicology
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph., Pharm.D.
Professor of Pharmacy Practice
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Cincinnati, Ohio

Goals

The goals of this lesson are to discuss the etiology and predisposing factors that lead to vaginal candidiasis infections, and identify specific treatment regimens.

Objectives

At the conclusion of this lesson, successful participants should be able to:

1. identify the characteristics of a normal vaginal physiology;
2. recognize the definitions of *yeast* and *candidiasis* and the microbial organism most likely to be at cause;
3. select the ingredients that are included in vaginal antifungal products and their pharmacologic and toxicologic considerations;
4. determine the therapeutic considerations of antifungal drugs that can be reviewed when choosing an appropriate product; and,
5. demonstrate the ability to counsel women on products intended for treating vaginal yeast infections.

A professional development program made possible by an educational grant from

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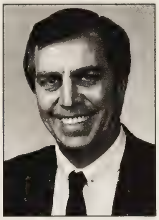

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Vaginitis is reported to be the most common complaint of women visiting gynecologists. It is estimated that 75 percent of all adult women in the U.S. will experience vaginal candidiasis at some time during their life.

Physiology of the Normal Vaginal Tract

The normal flora of the vaginal tract contains a mixture of aerobic and anaerobic bacteria including those of the genera *Bacteroides, Gardnerella, Staphylococci,* and *Streptococci.* Doderlein's bacillus, an acidophilic lactobacillus, is also present, and is described as the most important microbe because it metabolizes epithelial glycogen into lactic acid. The vaginal pH is normally alkaline before menarche (beginning of menstruation) and after menopause, and acidic during the childbearing years as a result of bacterial production of lactic acid. The vaginal pH extends from 3.0 to 6.1 with an average range of 3.5 to 4.2. This acidic pH, along with the presence of a normal bacterial flora, usually preclude pathogen growth. A pH shift toward alkalinity renders the vaginal tract more susceptible to infection.

Factors that Predispose to Infection

In up to one-half of asymptomatic women, *Candida* can be cultured from vaginal secretions. In the U.S., *Candida vaginitis* (20 to 25 percent of cases) is second only to bacterial vaginitis (40 to 50 percent of cases) as a cause of symptomatic vaginitis. Of women diagnosed as having candidal vulvovaginitis, *Candida albicans* can be isolated in 85 to 90 percent of cases.

Factors that have been associated with the development of candidal vulvovaginitis (inflammation of the vulva and vagina) include the taking of medications, the presence of underlying diseases, and pregnancy. Medications most frequently associated with increased risk for candidal infection include corticosteroids, oral contraceptives, broad-spectrum systemic antibiotics, and cytotoxic and immunosuppressant drugs.

Many antibacterial agents have the potential to promote fungal overgrowth. Most frequently implicated are amoxicillin, cephalosporins and tetracycline derivatives. Chronic therapy with systemic antibiotics may alter the body's natural flora and result in increased candidal colonization and growth. Cytotoxic and immunosuppressant drugs and corticosteroids alter immune status, thereby predisposing the patient to infection by *Candida*.

The vaginal epithelium is less resistant to infection before menarche and after menopause. Pregnancy and pseudopregnancy conditions, induced by oral contraceptives, increase the vaginal glycogen content which, in turn, is reported to predispose women to microbial infections. In addition, some researchers have demonstrated an increase in the adherence of *Candida* organisms to the vaginal epithelium during pregnancy.

The association of increased candidal vaginitis with oral contraceptive use is debated. There is suggestive evidence. But when various forms of contraception are compared, there is little difference. While older contraceptive products containing greater estrogen activity increase candidal colonization, recent studies involving low-estrogen agents fail to support this observation.

Diabetes mellitus predisposes the patient to increased candidal colonization and may increase the risk of symptomatic infection in these patients. Cushing's disease, Addison's disease, and hypo- or hyperthyroidism also seem to influence the development of a pathogenic state. Candidiasis also occurs with increased frequency in immunocompromised patients with impaired cellular immunity, especially those with organ transplants and those with acquired immunodeficiency syndrome (AIDS).

Excessive douching, and the wearing of tight-fitting clothing and occlusive nylon undergarments create an atmosphere conducive to survival of *Candida* and increase the risk of vaginal candidiasis. It has also been suggested that washing with cold water does not destroy *Candida*.

Symptoms of Vaginal Fungal Infections

The classic symptoms of a vaginal candidiasis (candidosis, yeast) infection include extreme itching, burning, vaginal soreness, irritation, and a curdy, off-white discharge. For some women, constant symptomatology can lead to sexual dysfunction and marital discord, and general decrease in the quality of life. The severity of symptoms seems to vary significantly from patient to patient. The reason for this is unclear.

Recurrent Vaginal Fungal Infections

Recurrent vaginal candidiasis is defined as an occurrence of at least four episodes within 12 months. It is estimated conservatively that 45 percent of women who have a candidal infection will experience a second infection. These are reported either as separate episodes, or possibly recurring infections. Physicians may attempt to determine the causes of recurrent infections, but such efforts are often unsuccessful. Although one or more of the predisposing factors discussed earlier may be present, most women with recurrent candidiasis exhibit no particular risk characteristics.

Resistant subpopulations of fungal organisms may result in treatment failure. A controversial theory is that women who experience recurrent vaginal candidiasis may harbor an intestinal reservoir of *Candida* that leads to chronic reinfection from fecal-vaginal cross-contamination. Additionally, sexual transmission is touted by some as a means to promote recurrent infections. This explanation appears unlikely in the majority of cases, though, since most male partners do not exhibit symptoms of infection. Moreover, treating sexual partners has little effect on the incidence of recurrence.

Simple measures can reduce the incidence and severity of recurrent yeast infections. Avoiding nylon underwear and tight-fitting clothing is suggested. Women taking oral contraceptives may wish to consider an alternative method of birth control. Recurrent infections may need to be treated with longer courses of therapy. In addition, some practitioners promote prophylactic administration of antifungal agents, including topical products during menstrual cycles. Others advocate concomitant antifungal therapy during courses of broad-spectrum antibiotic treatment.

Treatment of Vaginal Candidiasis Infections

Topical intravaginal antifungal products are currently the therapy of choice for vulvovaginal candidiasis. Nystatin was the first vaginally-applied agent found to be active against yeast fungi. It was the preferred treatment before discovery of the imidazole compounds. Nystatin is a polyene antifungal for intravaginal use. Nystatin damages the cytoplasmic membrane of fungi and is reported to be effective in approximately 80 percent of all cases of vaginal candidiasis. Other polyenes giving similar results are amphotericin B (Fungizone) and natamycin (Natacyn).

Imidazole Derivatives. There are currently four imidazole derivatives available in the U.S. for treating candidal vaginitis: butoconazole, clotrimazole, miconazole, and tioconazole (Table 1). The first three drugs are available OTC as of June 1996. The manufacturer of tioconazole had filed for a switch of Vagistat 1, but had not yet received approval as of that time. Terconazole, available by prescription, is often

Table 1
Vaginal Antifungal Products

Generic Name	Brand Name	Dosage Form/Strength	Status
Clotrimazole	Gyne-Lotrimin Mycelex-7	100mg vaginal tablet	OTC
Clotrimazole	Gyne-Lotrimin Mycelex 7	1% vaginal cream	OTC
Clotrimazole	Mycelex-G	500mg vaginal tablet	Rx
Miconazole	Monistat 7	100mg vaginal suppository	OTC
Miconazole	Monistat 7	2% vaginal cream	OTC
Miconazole	Monistat 3	200mg vaginal suppository	OTC
Butoconazole	Femstat 3	2% vaginal cream	OTC
Terconazole	Terazol 3	80mg vaginal suppository	Rx
Terconazole	Terazol 3	0.8% vaginal cream	Rx
Terconazole	Terazol 7	0.4% vaginal cream	Rx
Tioconazole	Vagistat 1	6.5% vaginal ointment	Rx*
Nystatin	Mycostatin	100,000 unit vaginal tablet	Rx

*Manufacturer had applied for OTC status at the time of preparation of this table.

grouped with the imidazoles, but is classified more appropriately as a triazole derivative. These products are available as vaginal creams, suppositories, and tablets. Extensive studies have demonstrated that the imidazole derivatives are effective in approximately 90 percent of patients without major toxicities. Studies have confirmed that terconazole possesses comparable efficacy.

Other Topical Agents. Other agents that have been used to treat candidiasis include 1 to 2 percent gentian violet and/or other dyes, povidone-iodine, boric acid powder and capsules, and *Lactobacillus* preparations. They have the disadvantage of being messy and unpleasant. In addition, a number of nonprescription vaginal preparations may afford symptomatic relief, but they do not affect the level of fungal organisms. Home remedies, including vaginal douches of yogurt or vinegar, have also been used to treat vaginal candidiasis. They have not been proven to be effective.

Use of these agents has decreased due to the effectiveness and safety of the imidazole derivatives. Advantages of the newer agents include superior efficacy and improved patient compliance associated with ease of use, fewer adverse effects, and shortened treatment durations.

Pharmacology of Vaginal Antifungals. The property of the imidazole and triazole compounds that affords antifungal action is alteration of the membrane permeability of susceptible fungi. They are active because they inhibit cytochrome P-450 enzymes in the fungal cell membrane, thereby decreasing synthesis of ergosterol, an essential fungal sterol. The reduced content of membrane ergosterol is accompanied by a corresponding increase in lanosterol-like methylated sterols. These lanosterol-like sterols incite structural and functional damage to fungal membranes, resulting in loss of normal membrane function.

The topical intravaginal antifungal agents are not absorbed appreciably. One study demonstrated that vaginal application of clotrimazole resulted in 3 to 10 percent of doses being absorbed systemically. This study also revealed that fungicidal concentrations of the drug were detectable in vaginal fluid for up to three days after a single 500mg intravaginal dose. A study of radiolabeled miconazole administered intravaginally demonstrated that approximately 1 percent of the dose was excreted in the urine, and the radioactivity level of whole blood was too low for measurement.

Topical imidazole and triazole derivatives are associated with vaginal burning, itching and irritation. Abdominal cramping and allergic reactions are reported rarely. Toxicity from topical therapy is minimal.

Treatment Regimens for Vaginal Candidiasis. The topical imidazole and triazole derivatives offer similar success rates in the treatment of candidal vulvovaginitis. A variety of treatment durations has been advocated. Initially, 14-day treatment regimens were recommended, and this is still prescribed for nystatin therapy. Durations of treatment for other therapies include seven days, three days, and a single-dose regimen which is approved for the 500mg clotrimazole vaginal tablet or tioconazole vaginal ointment dosage forms.

Some of the three-day and single-dose regimens demonstrate equivalent efficacy. However, these regimens have not been studied extensively in pregnant women or patients with complicated infections and/or presence of other predisposing factors.

As discussed previously, pregnant women have both an increased risk of candidal vaginitis and decreased response to therapy. Most short-course treatment regimens (i.e., one to three days) have not yet been shown to be as efficacious in pregnant women as in nonpregnant women. As a result, the duration of therapy during pregnancy should be at least seven days. Limited data are available on the safety of these products during the first trimester of pregnancy, and a physician must weigh risk versus benefit before therapy is instituted.

Systemic therapy with ketoconazole or fluconazole has been investigated thoroughly.

Table 2
Patient Counseling Advice for OTC Topical Antifungal Vaginal Products

General Information

- These products are used to treat vaginal yeast infections (candidiasis), after diagnosis by a doctor. If this is the first time you have experienced vaginal itch or discomfort, consult your doctor.
- Strictly follow instructions for proper use enclosed in the package for at least seven days, or three days for Femstat 3 and Monistat 3. Insert high into the vagina except during pregnancy.
- Complete the full course of therapy. Use continuously, even during your menstrual period.
- If symptoms worsen or persist longer than three days, or if you have constant irritation, such as burning or itching that was not present before you started this medicine, call your doctor.
- Do NOT use this medicine if you have abdominal pain, fever, or foul-smelling vaginal discharge unless directed by your doctor.
- If you have been exposed to HIV and are having recurrent vaginal infections, consult your doctor.
- Refrain from sexual intercourse during treatment or your male partner should use a condom to avoid the risk of infection. However, the cream used in some products may weaken certain latex products such as condoms or diaphragms. It is best to refrain from sexual intercourse for at least 72 hours after treatment.
- Wear a sanitary napkin to prevent staining of clothing due to seepage or leakage.
- Do NOT keep or use outdated medicine. Keep all medicines out of the reach of children and do not use this product in girls under 12 years of age without first consulting a doctor.

Vaginal Creams

- To open the tube, puncture the closure inside the cap with the point of the cap. Screw the applicator onto the tube. Squeeze the tube from the bottom until the plunger is extended out to the appropriate mark for the proper dose. Unscrew the filled applicator from the tube and insert the barrel gently into the vagina. Push downward as far as it will comfortably go.
- This is easiest when lying on your back with your legs spread apart and knees bent.
- Push the plunger all the way to deposit the cream deep into the vagina. With the plunger still pressed, remove the applicator.
- Take the applicator apart and wash the two parts with soap and lukewarm water, then dry it. Reassemble it by gently pushing the plunger back into the barrel as far as it will go. Place the cap on the tube and close it tightly.

Vaginal Suppositories and Tablets

- Read all the directions provided by the manufacturer for proper use.
- Wash your hands with soap and water before and after using this product.
- Cleanse the vaginal area and pat dry. Remove the wrapper from the medicine. Moisten the tablet/suppository with warm water. When an applicator is used, place the small end of the tablet/suppository into the applicator.
- Lie on your back with your knees bent and slightly spread apart. Insert the barrel of the applicator gently into the vagina. Push downward as far as it will comfortably go.
- Press the plunger gently to deposit the tablet/suppository into the vagina. With the plunger still pressed, remove the applicator.
- Take the applicator apart and wash the two parts with soap and lukewarm water, then dry it. Reassemble it by gently pushing the plunger back into the barrel as far as it will go.

Studies of 200mg doses of ketoconazole taken one or two times daily for three to six days and single doses of 150mg fluconazole have demonstrated efficacy comparable to that of topical therapy. Fluconazole can be administered as a single oral dose because of its long elimination half-life.

Oral therapy may increase compliance because of the relative ease of administration. However, neither ketoconazole nor fluconazole have demonstrated clear superior effectiveness over the topical imidazole derivatives. They possess greater potential to induce systemic toxicity and drug interactions. Systemic agents inhibit human cytochrome P-450 enzyme systems, as well as those of fungi.

Adverse effects from systemic antifungal therapy are more significant. Those reported with oral ketoconazole are nausea and vomiting. Hepatotoxicity has also been noted. Fluconazole is associated with nausea and vomiting. Other adverse effects reported for systemic agents include transient headache, skin rash and hives, diarrhea, dysuria (painful or difficult urination), dyspareunia (painful coitus) and abdominal pain.

Counseling Patients on the Treatment of Vaginal Candidiasis Infections

Any woman contemplating self-therapy should be certain that she has experienced the same symptoms previously and received a diagnosis of candidal vaginitis from a physician. The presence of fever (above 100° F orally); foul-smelling vaginal discharge; or pain in the lower abdomen, back, or shoulder are reasons to refer a woman to her physician. These signs and symptoms may be indicative of a systemic and more severe infection. Women should also be referred to a physician when vaginal symptoms return within two months. Pregnant women should not use nonprescription antifungal products without consulting a physician. The vaginal antifungals should not be used by persons under 12 years of age, unless directed by a physician.

Women should be questioned to determine whether any of the underlying risk factors that predispose to vaginal candidiasis are present. By obtaining a complete medication history, it is possible to determine whether the patient is receiving any medication that may increase the risk of developing candidiasis. A medication history may also alert the pharmacist to specific disease states associated with an increased risk of candidiasis.

Patients should be questioned about the possibility of pregnancy. The incidence of candidiasis is almost twice as high in pregnant women as in those who are not pregnant. Symptomatic pregnant women should be referred to a physician before initiating self-treatment for vaginal candidiasis.

Directions for proper use of the product should be discussed. The patient should also be informed of potential local reactions, including temporary burning, itching, and irritation. Instructions on when to stop using the antifungal product and when to call her physician should be offered, specifically if she develops abdominal cramping, headache, urticaria, hives, or skin rash.

Pregnant women or those with a history of sensitivity to any of the product ingredients should avoid using nonprescription antifungals without consulting a physician. Patients with any of the following symptoms should seek medical advice: fever, abdominal or back pain, or foul-smelling discharge. Patients should be referred to a physician if there has been no improvement after three days of therapy, if symptoms are resolved incompletely after the seven-day course, or if they recur within two months of stopping therapy.

Nonprescription topical imidazole therapy requires the proper selection and use of these products including dosage forms. General points are summarized in Table 2.

Efficacy, safety, patient acceptance, and cost of therapy must be considered before selecting an antifungal treatment. When specific products have equal effectiveness, the choice of a vaginal suppository, tablet, or cream can be left to the patient. There is little evidence that the choice of formulation influences clinical outcome.

An appropriate approach to managing the patient with vaginitis is listed in Table 3. With proper advice and consultation, many patients with uncomplicated infectious vaginal candidiasis can be managed safely and appropriately.

Table 3
Managing a Patient with Vaginal Infection Symptoms

First Episode
Refer to physician

Fever, Abdominal or Back Pain, Rash, or Foul-smelling Discharge
Refer to physician

Symptoms Previously Diagnosed by Physician as Yeast Infection

- Pregnant patient or patient younger than 12 years of age
  Refer to physician
- Pregnant patient or patient younger than 12 years of age with symptoms returning within two months
  Refer to physician
- Patient not pregnant and older than 12 years of age with symptoms returning within two months
  Recommend OTC antifungal product

Adapted from West DP and Maddux SV: Topical Anti-Infective Products, *Handbook of Nonprescription Drugs* 10th Ed., APhA, Washington DC, pp 493-510.

Money Minute

Furnished by
American Express Financial Advisors, Inc.
MaryBeth Miller, CFD

Giving to Your Grandchildren

As Jane sliced into the chocolate icing on her 70th birthday cake, she had much to celebrate -- good health, loyal friends and a comfortable home for herself. Her four college-age grandchildren even surprised her by showing up from out of town for the event.

Jane initially planned to take care of her grandchildren's future needs by passing her ample estate to her two sons. However, she changed her mind when she learned that one son, a high-school teacher, had to borrow against his retirement savings to pay his children's tuition.

Jane wanted to help, but in a way that treated her other son and his children equally. After listening to Jane's goals, her American Express financial advisor suggested she make annual gifts that skip a generation.

Thanks to a concept known as the gift-tax annual exclusion, Jane can give up to $ 10,000 (income- and gift-tax free) to each grandchild annually. She can even exceed that limit by writing tuition checks (gift-tax free) directly to her grandchildren's schools.

Under this exclusion, Jane is able to give her grandchildren tax-free gifts today. If she were to wait, estate taxes could reduce each bequest by as much as 40 percent. As she helps one preserve his retirement assets, Jane is sparing the other future estate taxes that would result if she gave the money to him instead of his children.

With her grandchildren taken care of, Jane is now considering additional ways she might reduce her estate tax burden. Gifting to her sons or daughters-in-law would be one way to reduce her net worth to the tax-free $ 60,000 level. Another option would be to help out a favorite nonprofit organization. Whatever else she decides, Jane is content knowing she has treated everyone equally and at a time they needed it most.

Estate-Planning Options to Consider:

Living trusts: Establishing a trust now can ensure the proper management of your estate and reduce administrative expenses.

Lifetime giving: Giving portions of your estate now may have significant tax advantages.

Charitable bequest: A bequest to a qualified charity can reduce estate taxes.

Reverse mortgage: In some states, you may draw monthly income from the equity in your home with this type of loan.

Frank Block, P.D.

On December 22, 1996 Frank Block died at the age of 92. Most of those 92 years were intertwined with the fortune of Maryland Pharmacy.

A graduate of the two year Maryland College of Pharmacy, he officially entered Pharmacy in 1924. Dr. Block was deeply involved in helping to resolve the social, ethical, and economic turmoil evolving in pharmacy, medicine, and government. For ten years he served ably as chairman of a legislative committee that provided us with many of the laws now affecting pharmacy practice. Recognized for his efforts by his colleagues, he was elected president of BMPA, MPhA , and the University of Maryland Pharmacy School Alumni Association.

Though he was among the brightest and the best of his time, he was a modest man who did not boast of his accomplishments. Many are aware of his contributions; the pharmacy profession will miss him.

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Continuing Education Quiz

March / April 1997

This month's questions are taken from the article on "Patient Counseling on Treatment of Vaginal Yeast Infections". Circle your answers to the following questions and mail the entire page to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members $ 10.00). The completed quiz for this issue must be received by 8/15/99. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly.
ACPE# 129-144-96-008-H01

Name ____________________________________

Address __________________________________

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The Maryland Pharmacy Continuing Education Coordinating Council and the Ohio Pharmacists Foundation are both approved providers of continuing pharmaceutical education for pharmacists by the American Council on Pharmaceutical Education.

1. The vaginal tract is more susceptible to infection when the pH is:
   a. acidic.
   b. alkaline.

2. The action of imidazole antifungals on fungi is to decrease the formation of fungal membrane:
   a. cholesterol.
   b. ergosterol.

3. Of the following, which is LEAST associated with an increased risk for candidal infections:
   a. antibiotics.
   b. corticosteroids.
   c. estrogens.
   d. immunosuppressants.

4. Which of the following antifungals is approved for a one-dose regimen?
   a. Miconazole
   b. Nystatin
   c. Terconazole
   d. Tioconazole

5. Which of the following is LEAST likely to be present in the normal flora of the vaginal tract?
   a. *Bacteroides*
   b. *Candida*
   c. *Gardnerella*
   d. *Staphylococci*

6. Women experiencing which of the following vaginal symptoms should seek the advice of a physician before self-medicating for a recurrent vaginal yeast infection?
   a. Curdy, off-white discharge
   b. Fever and abdominal pain
   c. Itching and irritation
   d. Vaginal soreness

7. The mechanism of action of nystatin in treating vaginal infections is:
   a. destruction of fungal cytoplasmic membranes.
   b. interference with ribosomal DNA polymerase.
   c. inhibition of nucleic acid synthesis.
   d. detergent action on lipoprotein binding groups.

8. The important organism in the normal flora of the vaginal tract that metabolizes epithelial glycogen into lactic acid is:
   a. Doderlein's bacillus.
   b. Epstein-Barr virus.
   c. *Gardnerella vaginalis.*
   d. *Proteus mirabilis.*

9. The mechanism of action for imidazole antifungals is inhibition of:
   a. cytochrome P-450 enzymes.
   b. glucose-6-phosphate dehydrogenase.
   c. monoamine oxidase.
   d. reverse transciptidase.

10. Which of the following products contains the same active ingredient as Gyne-Lotrimin?
   a. Femstat
   b. Monistat
   c. Mycelex
   d. Terazole

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In order to provide you with the legal information you need to practice in Maryland, the Maryland Pharmacists Association (MPhA) and the Maryland State Board of Pharmacy have collaborated to create a special publication entitled ***"Pharmacy Laws and Regulations for the State of Maryland".***

Every two years, each DEA registrant is required by both state and federal law to conduct a complete inventory of all controlled substances in their possession on May 1. Depending on when the DEA license was obtained, your inventory may be required on odd years or on even years. To help its members to comply with the law, MPhA has created the publication, ***"The Controlled Substance Inventory".***

To order either publication call the MPhA offices @ 410-727-0746 or 800-833-7587

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What pharmacists ought to know...

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Community Pharmacist Management Program

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MARYLAND Pharmacist

Volume 73, No. 3 May / June 1997

CONTINUING EDUCATION:
"Patient Counseling on Topical Analgesic Therapy for Arthritis Pain, Part I: Introduction"

PRESIDENT'S COLUMN:

UPDATE ON FEDERAL AND STATE PHARMACY LAW:

STUDENT ARTICLE:
Where Do We Go From Here?

NEW TOOLS FOR A New Century

The 115th Annual MPhA Convention

June 15 - 18, 1997
Ocean City, MD

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President's Commentary

One voice

Ernest Testerman, P.D., President

- ***Why does pharmacy not speak with One Voice?***
- ***When will different pharmacy groups come together and speak as one?***
- ***Will the pharmacy profession ever present a unified front?***

These are the questions the pharmacists I met this past year frequently asked me. Is it possible for pharmacy to achieve such a goal?

Pharmacy is such a diverse group of professionals that such a goal is monumental. We know the concerns of employee pharmacists are not totally the same as their employers. We also know the concerns of pharmacists are not totally the same as manufacturers, schools of pharmacy, boards of pharmacy, and insurance companies. With such diversity among a group of professionals, is it possible to have ***One Voice*** for pharmacy?

Many pharmacy organizations believe they know the ideas of pharmacists and can be this ***One Voice***. However, these organizations primarily promote the concerns of their particular group of pharmacy practioners. This type of promotion often creates hard feelings among other practioners in different practice settings. So, what is the solution to our problem?

The state pharmacy organizations could possibly be this ***One Voice*** of pharmacy. These organizations are composed of pharmacists from all types of pharmacy settings. This could be the ideal setting where concerns and expectations for pharmacy could be compiled and formulated into solutions for all of pharmacy. Yet again, each state has its own agenda which could cause hard feelings among pharmacists from other states.

Maybe the APhA could be the ***One Voice*** of pharmacy. It is the national organization of pharmacy composed of the state organizations, schools of pharmacy, manufacturers, and individual pharmacists from different practice settings and states. However, not all pharmacists belong to the APhA, so what do we do?

Maybe it is time to look outside for help for the pharmacy organizations, to get an outside party without emotional ties to the issue to formulate a ***One Voice*** policy. I believe we need to find the universal concern of pharmacists so we can all have a goal to stand behind and promote as pharmacists. We have had a tough time trying to find the issue for pharmacy from within so perhaps it is time to look outside the profession for help. Once this issue is found, we need to promote it with ***One Voice*** via our pharmacy organizations or through the outside source.

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A Thyroid Health Initiative

Quick Facts About Thyroid Disease

Thyroid Disease - What Is It? Who Is At Risk?

- Thyroid disease is an endocrine disorder best treated by a clinical endocrinologist or thyroidologist.
- The most common thyroid disorders are classified as *hypo*thyroidism, which usually occurs when the thyroid does not produce enough hormone, and *hyper*thyroidism, which results from an overactive thyroid gland.
- Approximately one woman in eight will develop a thyroid problem during her lifetime.
- Patients with other autoimmune disease and those with a family history of thyroid dysfunction are at increased risk for developing thyroid disease.

How is Thyroid Disease Detected?

- The development of an ultra-sensitive thyroid function test, the new thyroid stimulating hormone (TSH) assay, has allowed physicians to identify and treat thyroid disease while it is still in the mild, subclinical stage.

Hypothyroidism, An Underactive Thyroid

- Hypothyroidism affects approximately six to eight million people in the U.S., half of whom are undiagnosed and suffering needlessly. It can occur at any age and is five to eight times more likely to occur in women than in men.
- Hypothyroidism is marked by feelings of fatigue, depression, weight gain, sensitivity to cold, hair loss and unusually dry skin. Untreated hypothyroidism can be confused with other conditions such as high cholesterol, depression or menopause.

Hyperthyroidism, An Overactive Thyroid

- Hyperthyroidism, or an overactive thyroid, affects one million Americans, most of whom are women.
- Hyperthyroidism can be caused by an over-functioning thyroid gland or unintended over-replacement of thyroid hormone. Symptoms of the condition include excessive nervousness, sleep disturbances, weight loss, heat intolerance and reduced menstrual flow. Untreated hyperthyroidism can result in liver abnormalities, angina and increased heart rate.

Signs and Symptoms of Thyroid Disorders

HYPOTHYROIDISM

Tiredness
Loss of interest and/or pleasure
Forgetfulness

Dry, coarse hair

Loss of lateral eyebrow hair

Puffy face and eyes

Goiter

Slow heartbeat

Dry skin

Cold intolerance

Weight gain

Heavy menstrual periods

Constipation

Brittle nails

HYPERTHYROIDISM

Nervousness
Irritability
Difficulty sleeping

Bulging eyes
Unblinking stare

Goiter

Rapid heartbeat

Increased sweating

Heat intolerance

Unexplained weight loss

Scant menstrual periods

Frequent bowel movements

Warm, moist palms

Fine tremor of fingers

Provided by: The South Carolina Pharmacists Association

Directors Column

Much Ado About . . . Everything!

Tracy L. Baroni, R.Ph., J.D.
Executive Director

I remember being separated from my then best friend Julie in kindergarten for talking during class. This talking trend has continued with me throughout my life. In sixth grade when I was punished for insisting that what I had to say was more relevant than the words of my teacher, you would have thought I would get the message. To add insult to injury for those of you who are forced to listen to me, I've been told I talk much faster than the average person. On a good day, about 60 words per minute I figure. You must realize by now that anyone who talks this much can also write/type a blue streak. So here goes, my thoughts on a myriad of subjects.

The legislative session has come and gone. The pharmacy legislative agenda was of phenomenal proportion at the beginning of the Session, a rainbow stretching over the horizon. As pharmacists working on and with the task force, we set out to right the wrongs of the pharmacy practice act. The wrongs of years of neglect, the wrongs which occurred, for the most part, prior to HMOs, managed care, and capitation. The initial rainbow stretched further than the eye could see - beyond day to day workflow, beyond the question of professional judgment, to the pot of gold: collaborative practice and the ability to be an integral player on the health care team.

And now it's time to create a pharmacy version of the end of the rainbow story. As you have undoubtedly heard tell, the collaborative practice pot o' gold was elusive during the 1997 Session, as pots of gold so often are. I believe, however, that we did reach the less renowned but still noteworthy pot of silver. As a profession, through the perseverance and dedication of all the pharmacy organizations in the State and with the help of pharmacist-Delegates Elliott and Bozman, we not only achieved much of the ultimate goal, but began marking the path toward the pot of gold looming on the horizon for 1998.

Now is the time for unity. We must remember for what it is that we strive. All licensed pharmacists who are able to meet the standards set by the Board should be permitted to enter into collaborative practice agreements. There can be no division based on degree, practice site, or specialty certification. In the upcoming Session, as in that just past, we must realize that the rainbow's end is for the benefit of the profession and patients, and not solely for personal gain.

The Association should take pride in the part it and its members played in Annapolis during the 1997 Session. As is evident from the Legislative Update on page 23, most of the positions taken by MPhA were reinforced by the actions of the General Assembly.

It's now time for us to look forward - to June, to Ocean City, to "New Tools for A New Century," and beyond. Information on MPhA's 115th Annual Convention starts on page 10. The Convention Committee, Board of Trustees, and Association staff have pondered, brain stormed, and researched to come up with what promises to be a Convention which provides lots of fun and networking, combined with more CE offerings than ever before. The hours of the exhibit hall have been changed to allow attendees time to talk to and thank the representatives of the companies present. Children's activities, including face painting, magic, juggling, and balloon sculptures will be going on outside the open exhibit hall, allowing parents to experience the exhibits without worrying about the kids. As an added bonus, David Brushwood, R.Ph., J.D., will be the featured speaker at lunch on Tuesday, June 17, sponsored by DuPont Pharmaceuticals. Mr. Brushwood will discuss pharmacists' legal liability and how to avoid malpractice. Add these new ideas and activities to the traditional crab feast and a wide variety of CE offerings, and I think you'll agree - this year could be the best MPhA convention yet!

Since we're on the subject of the new century, it seems an appropriate time to provide an update on the relocation of the MPhA offices from the Kelly Memorial Building to a new site at the corner of Saratoga and Pine Streets, just up the street from the School of Pharmacy. Members of the Building and Property Committee, Joe Kaufman, and I have been working with representatives of UMMS to determine the size and scope of the building. At this time, it is anticipated that the UMMS master plan will require demolition of the Kelly Building by October 1997. Meanwhile, plans for packing, moving, and storage continue.

And finally, I would like to take this opportunity to thank everyone who has helped me during the past year. As we all know, David Miller left big footprints to fill as he walked out of the Kelly Building last year. It has been a year of learning, changing, growing. From the people and groups who donated money to purchase new computers, to the students who helped label newsletters, to the members who called just to comment that they liked the new formats of the publications, to my staff who still operate the postage meter for me because I can't seem to get the hang of it. You have all helped to make the transition smoother than it would have been otherwise.

As I leave footprints outside the Kelly Building for the last time on June 14, I anticipate mixed emotions: the anxiety that comes with starting something new, the desire to stay where I am now comfortable, and the determination to make my reservations early enough to always get a window seat (flying is bad enough, but you never realize how frequently nature calls to untrained, non-pharmacist bladders until you sit in the aisle seat!). I hope to continue to work with at least a few of you in my new position, and I encourage you to contact me if I can be of assistance. *Carpe Diem.* And with that, it's happened. I'm speechless.

ECKCEPTIONAL

Eckceptional. *What's in a name? When the name is Eckerd, the answer is a lot. We are a Fortune 100 company with 2,800 stores throughout the northeast and sunbelt with $9.5 billion in sales. Eckerd stands out as the second largest drugstore chain in the nation. Our stores foster an atmosphere of teamwork and support. Our customers view us as professionals. And with us, our Pharmacists enjoy challenges and advantages unlike any other.*

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NEW TOOLS FOR A *New Century*

That's the theme for MPhA's 115th Annual Convention. It's a reflection of the exciting new direction that your professional association is taking to meet your needs today and tomorrow. MPhA has planned a challenging series of continuing education programs focusing on the issues facing pharmacists. In addition, we've provided for lots of time to relax and enjoy the beach at Maryland's premiere resort.

This year, MPhA convention attendees can earn more than 13 continuing education credits toward their licensure renewal requirement. Our business meetings have been scheduled to give everyone a chance to participate in the Association's policy decisions. If you've never attended an MPhA Convention, this is definitely the year to give it a try.

If you have any questions about the program, accommodations or registration, please don't hesitate to contact the MPhA offices at (410) 727-0746 or toll-free in Maryland at (800) 833-7587.

REGISTRATION

To register for the 115th Annual Convention of the Maryland Pharmacists Association, complete the registration form included with this packet. Please print or type clearly. Return the entire form, with your check or credit card information for the total convention registration, to the address listed at the bottom of the form. You can also FAX your registration to MPhA at (410) 727-2253. Admission to all functions will be by ticket or badge. Pick up badges and other registration materials at the MPhA Registration Desk beginning Sunday, June 15 at 1:00 pm or on Monday, June 16 beginning at 7:30 am. You must register for the MPhA Convention to take advantage of special convention hotel rates. Spouses or guests must register to participate in any convention special activities.

Full Adult Registration (Pharmacist, Spouse/Guest, Non-Member) includes tickets to all convention events. Child registration includes tickets to the President's Reception and lunches. Student registration includes tickets to the President's Reception, entrance to the Exhibit Hall, and lunches. Child and Student Registrations do not include Crab Feast or Banquet tickets. Admission to these events must be purchased separately. Children will not be admitted to the Exhibit Hall.

CANCELLATION POLICY

Cancellations received on or before June 1, 1997 will be subject to a $50.00 processing charge per transaction. Cancellations received after June 1, 1997 will be subject to a $75.00 processing charge per transaction. Fees for CPR Training are non-refundable.

ACCOMMODATIONS

Once again, the Maryland Pharmacists Association has been able to obtain discounted hotel rates for attendees at one of Ocean City's finest resort hotels.

In previous years, the hotel has sold out of reserved rooms at the special MPhA convention rate. Don't be disappointed! To reserve your room, call the Sheraton Fontainebleau Hotel at (800) 638-2100. Be prepared to provide the Reservations Agent with your name, dates of arrival and departure, type of room requested and the number in your party. Tell the Reservations Agent that you are with the MPhA Annual Convention to obtain the special room rate!

ROOM RATES

Rates are subject to 8 percent room tax. One night deposit is required to guarantee your reservation. Children under 17 stay free of charge in the same room as parents. Rooms are available for check-in at 3:00 pm. The Sheraton Fontainebleau accepts personal checks for deposit only. A 72-hour notice of cancellation or change is required.

Guest Rooms (per night)

Single/Double	$135
Triple	$150
Executive King	$155
Quad	$165
Studio Suites	$165
Cabana Suites	$260

Condominiums (per week)

Without Maid Service	$1,050
With Maid Service	$1,250

SUNDAY, JUNE 15

1:00 - 5:00 • *Registration*
First Floor Lobby Sheraton Fontainebleau Hotel

2:00 - 5:00 • *Welcoming Reception*
First Floor Lobby

6:00 - 8:00 • *Student/Trustee Dinner*
Sponsored By: ***Searle***
Location: Conference 6

7:00 - 9:00 • *Continuing Education ~ Wound Care*
This portion of the J&J educational series will provide attendees with an introduction to the wound healing process and effective wound care. A review of wound types and products available will assist pharmacists interested in practicing in both traditional and non-traditional settings. *0.2 CEU ACPE Credit*
Presenter: Antoinette Fiore-McTigue
Sponsored By: ***Johnson & Johnson Medical, Inc.***
Location: Conference 1, 2 & 3

8:00 - 11:00 • *Trade Show*
Location: Grand Ballroom

9:00 - 11:00 • *President's Reception*
Join President Ernest Testerman for food and fun to celebrate the completion of a successful year as the Association's 1996-97 leader.
Sponsored By: Local Pharmacy Associations
Location: Conference 1, 2, & 3

MONDAY, JUNE 16

8:00 - 5:00 • *Registration*
First Floor Lobby

7:30 - 9:00 • *Breakfast*
Sponsored By: ***Sheraton***
Location: First Floor Lobby

8:00 - 9:00 • *Continuing Education ~ Update on Drugs for Management of HIV Infection*
The new antiretrovirals approved by the FDA during 1996 and 1997 have given the treatment of HIV an entirely new outlook. Participants will learn mechanisms of action, side effects, dosing, and drug interactions associated with these new agents. *0.1 CEU ACPE Credit*
Presenter: Stephen Piscitelli, Pharm.D.
Sponsored By: ***Bristol Myers Squibb***
Location: Banquet 2B

8:00 - 10:00 • *ASCP Breakfast and Program*
What ASCP Can Do For the Community Pharmacist
Join the Maryland Chapter of the American Society of Consultant Pharmacists for breakfast and an overview of how the Society can benefit pharmacists not practicing in nursing homes. R.S.V.P. by June 1, 1997 to (800) 574-0865.
Presenter: Chuck Hunt, R.Ph.
Location: Conference 5 & 6

9:00 - 11:00 • *House of Delegates*
The first session of the Association's democratic governing body will be devoted to reports from MPhA's President, Treasurer, and Executive Director. Nominees will be sought for the positions of House Speaker and Vice-Speaker. Current Speaker Crystal King presiding.
Location: Conference 1, 2, & 3

9:00 - 11:00 • *SAMPA Brunch and Flower Show*
Location: Horizons Restaurant

11:00 - 2:00 • *Trade Exposition*
Location: Grand Ballroom

12:00 - 1:00 • *Lunch*
Location: Banquet Hall 1

1:00 - 3:00 • *Continuing Education ~ Management of Outpatient Pain*
In the first lecture in the Convention's Pain Management Focus sponsored by Purdue Frederick, attendees will review the problems confronting practitioners caring for ambulatory pain patients and learn to resolve the issues involved in treating these patients, including legal and clinical aspects. *0.2 CEU of ACPE Credit*
Presenter: Mark Cziraky, Pharm.D.
Sponsored By: ***Purdue Frederick Co.***
Location: Conference 1, 2, & 3

1:00 - 5:00 • *Continuing Education ~ Adult CPR Training*
This American Red Cross course will enable adults and children 12 and over to overcome any reluctance to act in emergency situations and to recognize and care for life threatening respiratory or cardiac emergencies in adults. Pharmacists interested in expanding their practice to include vaccine administration should attend. Those not registered as pharmacist-attendees must register and pay separately for this course, additional information is included on the registration form.
0.4 CEU ACPE Credit
Presenter: Bruce A. Ford
Location: Banquet Hall 2 & 3

3:00 - 5:00 • *Continuing Education ~ Pain Management in the Terminally Ill*
During the second lecture in the Pain Management Focus sponsored by Purdue Frederick, pharmacists will learn to distinguish between different pain presentations in terminal illness, and to perform accurate and complete pain assessments. Prophylaxis and treatment of adverse effects associated with pain management regimens and the accurate conversion between opioids and different routes of administration will also be discussed. *0.2 CEU ACPE Credit*
Presenter: Mary Lynn McPherson, Pharm.D.
Sponsored By: Purdue Frederick Co.
Location: Conference 1, 2 & 3

6:00 - 9:30pm • *Annual Crab and Chicken Feast*
Admission by ticket only
Location: Berlin Fire Hall

TUESDAY, JUNE 17

8:00 - 5:00pm • *Registration*
Location: First Floor Lobby

7:30 - 9:00 • *Breakfast*
Sponsored By: Sheraton
Location: First Floor Lobby

8:00 - 10:00 • *Continuing Education ~ Substance Abuse in Pharmacy*
This program, sponsored by the Pharmacists Education and Assistance Committee (formerly the PRC), will update attendees on the impact of substance abuse on the profession, re-acquaint them on detection of substance abuse, and describe how employers can utilize the services of the PEAC when impairment is detected. *0.2 CEU ACPE Credit*
Presenters: Milton Moskowitz, R.Ph.; Tony Tommasello, M.S. R.Ph.; Toni Plucinski Conner,R.Ph.
Sponsored By: ***The Pharmacists Education and Assistance Committee***
Location: Conference 1

8:00 - 10:00 • *Trustee Meeting/Breakfast*
Sponsored By: ***Pharmacia Upjohn***
Location: Breakers Pub

9:00 - 10:00 • *Continuing Education ~ Controlling Hypertension by the Year 2000*
For years, the goal has been to recognize hypertensive patients and encourage diet and drug compliance to control the disease. The advent of new information pertaining to hypertension and the availability of new therapies should bring this goal closer. Participants will learn about new therapies and how pharmacists can be a vital part of the "control by 2000" goal. *0.1 CEU ACPE Credit*
Presenter: Michele Overtoom, Pharm.D.
Sponsored By: ***Searle***
Location: Conference 2 & 3

10:00 - 12:00 • *House of Delegates*
House Speaker Crystal King and Vice-Speaker Joe DeMino will preside over the second business session. Resolutions to be considered by the House during this session must be submitted to House Secretary Tracy Baroni by 5:00 p.m. June 16.
Location: Conference 1, 2, & 3

10:00 - 12:00 • *SAMPA Brunch & Business Session*
Location: Horizons Restaurant

12:00 - 1:00 • *Lunch*
Location: Banquet Hall 1

1:00 - 3:00 • *Continuing Education ~ Management of Chronic Cancer-Related Pain and Non-malignant Pain*
The third lecture in the Pain Management Focus sponsored by Purdue Frederick will educate attendees in understanding pain, and will tell how to use that understanding combined with acceptable pain management principles to successfully relieve chronic cancer-related and non-malignant pain. *0.2 CEU ACPE Credit*
Presenter: Rosemary C. Palomano, Ph.D., R.N.
Sponsored By: ***Purdue Frederick Co.***
Location: Conference 2

1:00 - 3:00 • *Continuing Education ~ How Pharmacists Can Help the Nicotine Dependent Patient*
The May 1988 Surgeon General's Report identified nicotine as an addicting drug in the same category as alcohol, cocaine, heroin, and marijuana. Although many people have quit, those who continue to smoke are predominantly heavy smokers, and 90% began smoking in their teens. This course will help attendees understand the addiction and identify a course to follow in assisting these patients in overcoming their addiction. *0.2 CEU ACPE Credit*
Presenter: Thomas Cooper, D.D.S.
Sponsored By: ***SmithKline Beecham***
Location: Conference 3

NEW TOOLS FOR A
New Century

3:00 -5:00 • *Continuing Education ~ Pain Management in the Elderly*
The final session in the Pain Management Focus sponsored by Purdue Frederick will concentrate on the prevalence of inadequate pain control in the elderly. Participants will learn the various etiologies of pain specific to this population and how to select appropriate medications and dosing schedules based on the etiology of the pain and patient-specific factors. *0.2 CEU ACPE Credit*
Presenter: F. Michael Gloth, III, M.D.
Sponsored By: ***Purdue Frederick Co.***
Location: Conference 2

3:00 -5:00 • *Continuing Education ~ Internet 101 For Health Care Professionals*
This program will familiarize attendees from all disciplines with the Internet and the amazing impact it can have on all practice settings, as well as on patient care. Attendees will learn how to evaluate and purchase hardware and software and how to utilize Internet technology in their personal and professional lives. *0.2 CEU ACPE Credit*
Presenter: Michael S. Brown
Sponsored By: ***GlaxoWellcome***
Location: Banquet Hall 2B

6:00 -7:00 • *Banquet Reception*
It wouldn't be a convention without the pre-dinner cocktail reception. Open bar and plenty of hors d'oeuvres will be the beginning of an evening of fun and festivity.
Location: Salon B

7:00 -9:00 • *Awards Banquet*
Celebrate the end of another successful MPhA Convention at our Annual Awards Banquet. We will be honoring the 1997 MPhA Award Recipients as well as our new officers and trustees. Don't forget to sign up for a table seat at the MPhA Convention Registration Desk on Monday or Tuesday. **Admission by ticket only.**
Sponsored By: ***McKesson Drug Co.***
Location: Salon A

9:00 -10:00 • *Dessert Reception*
For those with a sweet tooth and the urge to mingle, this reception is a must. Join Association and AmeriSource friends and colleagues while enjoying the lavish dessert buffet. **Admission by badge.**

WEDNESDAY, JUNE 18

8:00 - 9:00 • *Breakfast*
Location: Terrace Lobby

9:00 - 11:00 • *Continuing Education ~ Compliance with HIV-Associated Polypharmacy: A Heroic Endeavor*
The final CE program of the Convention will highlight the important role of pharmacists and pharmaceutical care in the treatment of HIV. Difficult drug regimens and the wide range of patient populations make pharmaceutical care a vital part of successful therapy, and also make making a difference a "heroic endeavor". Attendees will learn to expand the role of pharmacists while moving toward a future in which HIV becomes a manageable, chronic desease. *0.2 CEU ACPE Credit*
Presenter: Mark J. Shelton, Pharm. D.
Sponsored By: ***Merck & Co.***

The Maryland Pharmacy Continuing Education Coordinating Council is approved by the American Council of Pharmaceutical Education as a provider of continuing pharmaceutical education for pharmacists. The ACPE numbers assigned to this program are pending approval.

NEW TOOLS FOR A *New Century*

Registration

To register for the 115th Annual Convention of the Maryland Pharmacists Association, complete this registration form. Please print or type clearly. Return the entire form to MPhA at the address below or FAX it with credit card information to (410) 727-2253.

You must register with the MPhA Convention to take advantage of special convention hotel rates. Spouses, guests and children must register and/or purchase function tickets to attend any convention events.

Full registration includes admission to all meetings, social events and processing of continuing education credits. Spouse/Guest Registration includes admission to all social events, plus the annual SAMPA Flower Show and Brunch. Single Day registration includes breakfast, lunch, and processing of continuing education credits for that day only. Tickets to social events for Single Day Registrants must be purchased separately. Children must be formally registered to enter any social event. Children will not be permitted to enter the Exhibit Hall. Child and Student Registration fees do not include the Crab Feast or Banquet.

Questions?
Call: **800-833-7587**
or **410-727-0746**

Cancellation Policy

Cancellations received on or before June 1, 1997 will be subject to a $50.00 processing charge per transaction. Cancellations received after June 1, 1997 will be subject to a $75.00 processing charge per transaction. Fees for CPR Training are non-refundable.

MPhA
Maryland Pharmacists Association

Do you wish to serve as an MPhA delegate at the business sessions?
☐ Yes ☐ No

Maryland Pharmacists Association

115th Annual Convention
Sheraton Fontainebleau Hotel
June 15-18, 1997

Name ______________________________

Pharmacy / Company Name ______________________________

Mailing Address ______________________________

City / State / Zip ______________________________

Telephone ______________________________

Spouse / Guest Name(s) ______________________________

Children(s) Name(s) ______________________________

Registration Fees

Please check the appropriate box(s).

Full Registration	*Before June 1*	*After June 1*
MPhA Member	☐ $150	☐ $175
Spouse / Guest	☐ $120	☐ $140
Non-Member Pharmacist	☐ $225	☐ $250
Child Under 18	☐ $25	☐ $35
Pharmacy Student	☐ $25	☐ $35
Daily Registration		
MPhA Member	☐ $50	☐ $60
Non-Member	☐ $65	☐ $75
Extra Event Tickets		
Crab & Chicken Feast		
Adult / Students	☐ $40	☐ $45
Child Under 12	☐ $15	☐ $20
MPhA Annual Banquet		
Adult / Students	☐ $30	☐ $35
Child Under 12	☐ $20	☐ $25
SAMPA Events		
Flower Show / Brunch	☐ $15	☐ $20
Brunch / Business	☐ $15	☐ $20

CPR Registration

For non-pharmacist attendees, including children 12 and over.

______________ @ $35.00 per attendee = $________
No. of attendees **Total**

Grand Total $______________

☐ Enclosed is my check ☐ Bill my _____Visa _____MasterCard

Credit Card Number______________________________

Signature ______________________Expiration Date______________

SOCIAL EVENTS

This year's convention is full of excellent opportunities to network and socialize with your colleagues. From Sunday's Welcoming Reception to Tuesday evening's reception, banquet and desserts, you're certain to have a relaxing time!

And we guarantee you won't go home hungry! Join us every morning for breakfast, donuts and coffee during seminar breaks, lunches, and plenty of evening receptions and parties.

Keep up with the latest, most exciting developments and the newest products and services on the market at the MPhA Trade Exposition. Visit every exhibitor and enter to win the Grand Prize Sweepstakes!

Trade Exposition Past Exhibitors have included:

3M Pharmaceuticals
Alco Health Services Corp.
AMERICOM
Apothecon
Becton Dickinson
Bergen Brunswig
Boots Pharmaceuticals
Cardinal Health
Carex
Carlton Cards
Cerenex
Daniels Pharmaceuticals
Elegant Enterprises
Eli Lilly & Company
EPIC Pharmacies/MPPI
FoxMeyer
Fuji Trucolor Photofinishing
Geneva Pharmaceuticals
GlaxoWellcome
Goldline Laboratories
Hoechst-Roussel
Hudson Vitamins
Janssen Pharmaceuticals
Konica Quality Photo East
Lederle Laboratories
Marion Merrell Dow, Inc.
Mayer, Steinberg & Yospe
McKesson Drug
Medicine Shoppe Int'l
Merck & Company
Miles
Novo Nordisk Insulins
Owens-Brockway
Pfizer Labs
Pharmacia Upjohn
Pharmacists: prn
PharmaSTAT
Qualex
Ronins/Ives Labs
Roche Laboratories
RX Systems
Schein Pharmaceutical, Inc.
Schering Plough/Key Pharmaceuticals
Searle Pharmaceuticals
SmithKline Beecham
Travelers Express Company
UMAB School of Pharmacy
Valu-Rite
Warner Chilcott
Wyeth/Ayerst Labs
Zeneca Pharmaceuticals

Attention Pharmacists and Pharmacy Technicians

National Voluntary Certification for Pharmacy Technicians

1997 Examinations:

Saturday, March 22, 1997
Saturday, July 12, 1997
Saturday, November 8, 1997

Application Deadline:

January 24, 1997
May 16, 1997
September 12, 1997

Eligibility Requirement:

High School Diploma or G.E.D.

Exam Cost:

$105.00

For information and application material write:

PTCB
Pharmacy Technician Certification Board

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The Handbook of Collaborative Drug Therapy Management is a brand new publication designed to start you on the path to pharmaceutical care.

Written by Washington pharmacist Tim Fuller and published by the Washington State Pharmacists Association, this 88-page paperback is a practical "how to" guide that includes currently used templates to demonstrate how to enter into drug therapy agreements with authorized prescribers.

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1501 Taylor Avenue, S. W.
Renton, WA 98055-3139

Nicotine Poisoning

Cathleen Clancy, M.D., Medical Director
Maryland Poison Center

Case: A 2 year old boy was found lethargic and vomiting. He had been playing with a previously unopened pack of nicotine replacement gum. There were 8 to10 pieces of gum missing. Upon arrival of paramedics, the boy had a grand mal seizure.

Nicotine has been present in our environment since before Christopher Columbus visited the New World. Traditional sources of nicotine include cigarettes, cigars, snuff (moist and dry), chewing tobacco (loose, leaf, plug, twist, fine cut), and insecticides. Over the past few years, nicotine replacement products have become a common source of nicotine poisoning. Nicotine gum and patches are available over-the-counter and a nicotine nasal spray was recently released for prescription use.

Nicotine is rapidly absorbed through skin, alveoli, mucous membranes and gastrointestinal tract. Nicotine is water soluble; dermal absorption of dew from tobacco leaves has caused systemic toxicity.

One cigarette contains 8 to 20 mg of nicotine and a cigar contains up to 40 mg of nicotine. The gum and patches deliver between 2 and 20 mg of nicotine, although prolonged dermal or mucosal exposure is required for complete release. Each bottle of the nicotine spray contains 100 mg of liquid nicotine; however, each spray releases only 0.5 mg.

Mild symptoms usually occur following the ingestion of 2 to 5 mg of nicotine. Children have become symptomatic after chewing or swallowing just one piece of gum, more than one cigarette or more than 3 cigarette butts. The lethal dose for an adult is approximately 40 to 60 mg (0.6-0.9 mg/kg).

Patients with mild to moderate poisoning may present with the classic findings of acetylcholine excess from stimulation of the parasympathetic nicotinic and then muscarinic receptor sites. The clinical picture is similar to a patient poisoned by organophosphate insecticides. The mnemonic "SLUDGE", may be used to describe these cholinergic symptoms: Salivation, Lacrimation, Urination, Defecation, Gastrointestinal upset, Emesis. Confusion and oral irritation also are seen.

Severe poisoning is often seen following the ingestion of liquid nicotine preparations, usually insecticides. When high doses of nicotine are involved, blockade at the ganglion and neuromuscular junction develops. The receptors become refractory to stimulation by acetylcholine, similar to the effects of curare. Central nervous system depression and neuromuscular paralysis may develop. In a severely poisoned patient, mouth and throat burning, confusion, nausea and vomiting occur first and coma, seizures and respiratory arrest ensue rapidly. The signs of cholinergic excess appear to resolve.

The differential diagnosis of nicotine poisoning includes agents that produce signs of cholinergic toxicity and other agents that cause the rapid onset of seizures and and respiratory arrest. An organophosphate-poisoned patient may have signs of cholinergic excess with bronchorrhea but would not be expected to rapidly develop acute hypotonia as seen in a nicotine-poisoned patient. Other disease states such as meningitis, stroke and intracranial hemorrhage, cause seizures, coma and respiratory arrest but not cholinergic symptoms.

The laboratory evaluation of a patient with nicotine poisoning involves aggressive respiratory (pulse oximetry, arterial blood gases) and cardiac monitoring. Head CT and EEG may be useful adjuncts in the comatose patient without a clear history of nicotine exposure. Serum and urine assays for nicotine are available but are of limited value in the acute setting. Nicotine is seldom detected on a routine serum toxicology screen. Nicotine or the metabolite cotinine are sometimes qualitatively reported in comprehensive urine toxicology screens, however, positive results may be obtained in smokers and those exposed passively to tobacco smoke.

Decontamination and supportive care are the mainstays of therapy. In cases of dermal contamination, clothing must be immediately removed and the skin irrigated with copious amounts of water. Spontaneous emesis often occurs following acute ingestion of nicotine. Ipecac use is controversial since central nervous system depression and seizures occur with severe overdoses. If significant emesis has not occurred, gastric lavage should be considered. A large bore orogastric tube is necesssary to remove pieces of gum, patches or tobacco. Activated charcoal will decrease nicotine's absorption.

Early and aggressive respiratory support is crucial. Hypotension should be treated with fluids and vasopressors. Atropine may relieve the "SLUDGE" symptoms of parasympathetic stimulation, but is not indicated when ganglionic blockade develops. Urinary acidification does increase the urinary excretion of nicotine, but is not recommended. A large proportion of nicotine is hepatically metabolized and not renally excreted and the risks of systemic acidification outweigh the benefits.

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50	$570	$398	$1,090	$745

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Pharmacy Reimbursement Programs

Provided by: The Montana State Pharmaceutical Association

This is a synopsis of an article written by Karen Brauman, M.S., R.Ph., of the University of Kansas Medical Center. The subject of the article, Pharmacy Reimbursement Programs, was first brought to the attention of the Montana Pharmacists Association by MSPA Board Member, Jim Marmar.

Indigent patients represent 8% to 14%- sometimes as high as 20%- of inpatients treated at acute care hospitals, and up to 21% or more of patients in outpatients clinics. In many cases, the cost of treatment provided to these patients is absorbed by the institution. A significant portion of these costs represent pharmaceutical costs, especially as new medications (such as protease inhibitors) are used with increasing frequency. In the current health care environment, we are trying to identify ways to decrease costs wherever possible. One resource that has not been fully utilized to date is reimbursement assistance, through programs funded by pharmaceutical manufacturers.

Approximately 50 pharmaceutical manufactures provide reimbursement assistance programs, covering more than 250 prescription products. These programs assist in reimbursement for needed prescriptions for patients who qualify based on predefined criteria for indigence. Many programs have different eligibility criteria, different processes for patient enrollment, and different required shipping locations for the drug or for reimbursement. This lack of standardization and confusion related to these programs are probably the reasons this resource has remained largely untapped.

"If you can get one of your patients enrolled in one of these programs, you've made a friend (and customer) for life"...MSPA Board Member Jim Marmar.

The participating pharmacy retains the necessary licensure and controlled storage conditions to maintain and stock medications for indigent patients, and meet JCAHO requirements for drug inventory management and security.

Initially, pharmaceuticals that represent the greatest expense to the institution should be targeted for the reimbursement program. Depending on the pharmacy and the type of patients involved, these may include erythropoietin, colony stimulating factors, chemotherapy agents, immunosuppressants, and antimicrobial agents. Patient groups initially targeted to receive free medication may include transplant, HIV/AIDS, oncology, and dialysis patients. Once the program is organized and is handling these medications and patient groups efficiently, it can be expanded to include a larger number of pharmaceuticals and more outpatient groups.

Millions of dollars are written off annually by institutions providing indigent care. If a fraction of this can be saved by accessing pharmaceutical manufacturer assistance programs, it is worth the investment of time and organization. In addition to reducing hospital costs, such a program will also enhance public relations within the community.

A pharmacy coordinated program can standardize the means for acquiring medication for indigent patients, and improve the accessibility of these programs. A pharmacy-coordinated program should also improve compliance with prescribed medications in this population, which can be a problem due to the frequency with which they receive medication.

Such a program, when administered efficiently and with the appropriate documentation, will provide medications for financially disadvantaged patients, while providing substantial savings to the pharmacy. The pharmacy possesses the resources and qualified personnel to administer and maintain a formalized reimbursement assistance program. Coordination of an interdisciplinary effort to provide medication to indigent patients can achieve many goals including:

- Access to medications and improved medication compliance for the indigent population
- Reduce acquisition costs of pharmaceuticals
- Meeting JCAHO standards for interdisciplinary coordination of care to patients
- Enhanced public relations

Reimbursement Assistance Programs Available from Pharmaceutical Manufacturers are listed on pages 19 & 20.

Pharmaceutical Company	**Program**	**Phone Number / Fax**
ALZA Pharmaceuticals	ALZA Pharmaceuticals Indigent Patient Assistance Program	(415) 962-4297
Amgen, Inc.	Safety Net Program for EPOGEN®	(800) 272-9376 (202) 637-6698
	Safety Net Program for NEUPOGEN®	(800) 272-9376 (202) 637-6698
Astra Merck, Inc.	Indigent Patient Program	(800) 236-9933
Astra USA, Inc.	Foscavir® Assistance and Information on Reimbursement (FAIR)	(800) 488-FAIR (3247) FAX: (703) 683-2239
Bayer Corp. (formerly Miles, Inc.) Pharmaceutical Division	Bayer Patient Assistance Program	(800) 998-9180
Berlex Laboratories	Berlex Laboratories Cardiovascular Assistance Program	(800) 423-7539
	Betaseron® Indigent Patient and SUPPORT Program	(800) 788-1467
	Fludara® PACT (Patient Assistance for Cancer Treatment) Program	(800) 473-5832
Boehringer Ingleheim Pharmaceuticals, Inc.	Partners in Health	(800) 555-8317
Bristol-Myers Squibb Co.	Bristol-Myers Squibb Patient Assistance Program	(800) 736-0003 FAX: (703) 760-0049
Ciba Pharmaceuticals	Patient Support Program	(800) 257-3275
Connaught Laboratories, Inc.	Indigent Patient Program	(800) 822-2463
DuPont Merck Pharmaceutical Co.	DuPont Merck Pharmaceutical Co. Patient Assistance Program	*Contact Local Representative*
Fisons Pharmaceuticals	Fisons Respiratory Care Program	*Contact in Writing*
	Gastrocrom® Patient Assistance Program	*Contact in Writing*
Fujisawa USA, Inc.	NebuPent® Indigent Patient Program	(708) 317-8636 FAX: (708) 317-5941
	Prograf® Patient Assistance Program	(800) 4-PROGRAF (447-6472) (202) 393-5563
Genentech, Inc.	Uninsured Patient Assistance Program	(800) 879-4747 FAX: (415) 225-1366
GlaxoWellcome, Inc.	GlaxoWellcome Patient Assistance Program	(800) 722-9294 (800) 452-9677 FAX: (602) 314-7070
Hoechst Marion Roussel, Inc.	Indigent Patient Program	(816) 966-4000 (800) 362-7466
	HRPI Patient Access Program	(800) 422-4779
Janssen Pharmaceuticals	Janssen Patient Assistance Program	(800) 544-2987
	The Risperdal Patient Assistance Program/Reimbursement Support Program	(800) 652-6227 FAX: (602) 357-0036
Knoll Pharmaceutical Co.	Knoll Indigent Patient Program	*Contact in Writing*
Lederle Laboratories	Lederle PARTNERS IN PATIENT CARE™ Assistance Program	*Contact in Writing*
Eli Lilly and Co.	Lilly Cares	(800) 545-5962
McNeil Pharmaceutical	McNeil Patient Assistance Program	(800) 682-6532
Merck Human Health Division	Merck Patient Assistance Program	(800) NSC-MERCK (672-6372)

Pharmaceutical Company	**Program**	**Phone Number / Fax**
Ortho Biotech, Inc.	Financial Assistance Program (FAP™) for PROCRIT® (epoetin alfa) and LEUSTATIN® (cladribine) Injection/Ortho Biotech	(800) 553-3851
Ortho Pharmaceuticals Corporation	Ortho Pharmaceuticals Patient Assistance Program	(800) 682-6532
Parke-Davis	Parke-Davis Patient Assistance Program	(800) 755-0120
Pfizer Inc.	Pfizer Prescription Assistance	(800) 646-4455
	Diflucan® Patient Assistance Program	(800) 869-9979
	Sharing the Care	(800) 984-1500
	Arkansas Health Care Access Program (participant)	(800) 950-8233 (501) 221-3033
	Kentucky Health Care Access Program (participant)	(800) 633-8100 (502) 244-4214 FAX: (502) 244-4209
	Commun-I-Care (participant)	(800) 763-0059 (803) 779-4875 FAX: (803) 254-0320
Pharmacia Inc.	Pharmacia Patient Assistance Program	(800) 366-5570
Proctor and Gamble Pharmaceuticals Inc.		(800) 448-4878
Rhone-Poulenc Rorer Inc.	Rhone-Poulenc Rorer Indigent Access Program	(610) 454-8110 FAX: (610) 454-2102
Roche Laboratories	Roche Medical Needs Program	(800) 285-4484
Roxane Laboratories	Patient Assistance Program	(800) 274-8651
Sandoz Pharmaceuticals Corporation	Sandoz/NORD Drug Cost Share Program	(800) 447-6673
Sanofi Winthrop Pharmaceuticals	Needy Patient Program	(800) 446-6267
Schering Laboratories/ Key Pharmaceuticals	Commitment to Care	(800) 521-7157 (Intron A/Eulexin) (800) 656-9485 (All other products)
Searle	Patients in Need™	(800) 542-2526 FAX: (708) 470-6633
Serono Laboratories Inc.	Serono Laboratories' Helping Hand Program	(617) 982-9000 FAX: (617) 982-1369
SmithKline Beecham Pharmaceuticals	SB Access to Care Program	(800) 546-0420
	PAXIL Access to Care Program	(800) 729-4544
	Kytol/Timentin/Triastat Hospital Reimbursement Program	(800) 865-6273
Solvay Pharmaceuticals Inc.	Patient Assistance Program	(800) 788-9277
3M Pharmaceuticals	Indigent Patient Pharmaceutical Program	(800)528-0255 FAX: (612) 733-6068
The Upjohn Company	Upjohn Patient Assistance Program	(800) 242-7014
Wyeth-Ayerst Laboratories	Norplant Foundation	(703) 706-5933
	Wyeth-Ayerst Laboratories Indigent Patient Program	*Contact in writing*
Zeneca Pharmaceuticals	Zeneca Pharmaceuticals Foundation Patient Assistance Program	(800) 424-3727

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We are still accepting corporate sponsorships throughout the year. If your company is interested in participating, please contact the MPhA office at (410) 727-0746.

Federal Law Update

On March 24, 1997, the Drug Enforcement Administration (DEA) issued a final rule, effective March 28, 1997, which amends Title 21 Code of Federal Regulations (CFR) Sections 1300 through 1316. These amendments clarify, eliminate, and consolidate various DEA regulations. As always, pharmacists are required to follow both State and Federal law. Remember, if the state and federal laws differ, the more strict law must be followed.

Section 1304.04 Maintenance of records and inventories

Provides an exception to the requirements that pharmacies mark the hard copy of prescriptions for controlled substances in schedules III - V with a red "C" if automated systems are used where prescription information is "readily retrievable".

Section 1304.11(c) Biennial inventory date

Allows the biennial inventory for controlled substances to take place on any day within the calendar year that the inventory is scheduled. Previously, pharmacies were required to inventory controlled substances biennially within six months of the date of the previous inventory.

Section 1306.11(d)(4) Requirement of a prescription

Permits pharmacists to receive the original prescription for an order of an emergency supply of a schedule II controlled substance within seven days after receiving the emergency order. If the prescriber chooses to send original prescriptions for a schedule II controlled substance by mail, the carrier envelope must be postmarked within seven days of the original order. Previously, pharmacies were required to receive the original prescription within 72 hours after an emergency order was received by the pharmacy.

Section 1306.11(g): Requirement of a prescription

Allows facsimile prescriptions for schedule II controlled substances to act as the original prescription for patients in hospice settings that are "hospice certified under Medicare Title XVIII" or licensed by the state.

Section 1306.25: Transfer between pharmacies of prescription information for schedules III, IV, and V controlled substances for refill purposes

Permits pharmacies that share a "real-time, on-line electronic database" to transfer prescription information for controlled substances up to the maximum amount of refills permitted by law and the prescriber's authorization. Previously, pharmacies were allowed to transfer prescriptions for controlled substances between pharmacies only one time.

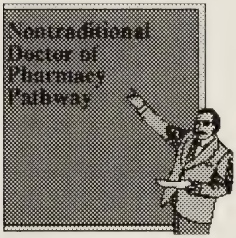
1997 State Legislation Affecting Pharmacy - Final

Title	Description	MPhA Position	Status
SB95 - Dispensing of Drugs and Devices by Health Department Nurses	Permits Health Department nurses to dispense drugs for family planing, sexually transmitted diseases, and TB to clinic patients.	Oppose	Killed
SB368 - Diabetes Equipment, Supplies, & Self-Management Training - Coverage	Requires insurers to cover diabetes equipment, supplies, and self-management training provided by appropriately licensed health care providers, including pharmacists	Support	Passed
SB326/HB277 - Health Occupations - Scope of Practice	Prohibits all professionals licensed under the Health Occupations Article, except pharmacists, from practicing on animals.	Support	Passed
SB579/HB210 - Physical Therapists - Scope of Practice - Topical Pharmaceutical Agents	Permits physical therapists to acquire RX drugs from wholesalers and to administer and dispense to patients pursuant to prescriber's order.	Oppose	Killed
HB 368 - Health Insurance - Maintenance Drug Prescriptions - Supply Quantity	Requires HMOs to cover a 100 day supply for maintenance drugs. Amendment requires pharmacists to be reimbursed an additional dispensing fee for every additional co-pay charged to the patient by the HMO.	Oppose	Passed
HB785 - Nurse Psychotherapists - Authority to Prescribe and Dispense Drugs	Permits nurse psychotherapists to prescribe psychotherapy drugs and dispense from office setting.	Oppose	Killed
SB652/HB1287 - State Board of Pharmacy - Scope of Practice SB664/HB1230 - Board of Pharmacy - Disciplinary & Regulatory Authority SB 717/HB1229-Board of Pharmacy - Composition	Pharmacy Practice Act revisions - permit pharmacists to refuse to fill a prescription (w/notification to prescriber); to refill a non-controlled maintenance drug for a 14 day supply (w/notification to prescriber); increases maximum fine for practicing pharmacy without a license; expands Board of Pharmacy to 10 pharmacists with designated seats	Support	Passed
SB1223 - Physician Assistant Prescribing	Permits PAs certified by BPQA to prescribe in inpatient and institutional settings with a co-signature required within 48 hours.	No Position	Passed
SB636 - Child Support Enforcement Procedures	Requires professional licensing boards to take action against licenses of persons delinquent in child support payments	No Position	Passed
SB325 - Medical Records - Maintenance, Disclosure, & Confidentiality	Adresses issues surrounding confidentiality of patient records, including incurrence of liability by provider for damages if medical records are released in violation of the law	No Position	Passed

Update on the Nontraditional Doctor of Pharmacy Pathway

Mary Lynn McPherson, Pharm.D., BCPS
Director, NTPD Pathway

Spring is in the air (albeit a little chilly some mornings), and everything is growing - including the Nontraditional Doctor of Pharmacy Pathway (NTPD) at the University of Maryland at Baltimore School of Pharmacy! We have once again received more applications that we can accommodate for the Fall 1997 entering class, and collectively they represent a very strong applicant pool. The continued response to the NTPD Pathway has been very gratifying and indicates that we are meeting the need of practitioners as they move into the twenty-first century. Our graduate pool is growing as well; in 1996 seventeen students received the Pharm.D. degree upon completion of the NTPD Pathway; this May twenty additional graduates earned degrees. These students have worked very hard for their degree, and we wish them continued success in their career.



As is the way with all programs, self-assessment and quality improvement is essential. Shortly after our first group of pharmacists graduated from the program in May 1996, the School's Curriculum Committee assembled an Ad Hoc group to formally evaluate the didactic courses and experiential requirements of the NTPD Pathway. After a lengthy study of student evaluations, informal feedback and recommendations from faculty teaching in the Pathway, curriculum revision suggestions were forwarded to the NTPD External Advisory Board (comprised of NTPD students and graduates) for review and discussion, then approved by the Curriculum Committee, and finally forwarded for approval by the school's faculty. At every step in the process, we received positive feedback. A summary of the changes to the Pathway are as follows.

Originally, the NTPD Pathway was designed with the goal of preparing practitioners to be better pharmaceutical care providers *in their own practice setting*. Consequently, the first course, *Principles of Pharmaceutical Care* was offered in two versions - *Community/Ambulatory*, and *Organized Health Care*. Students were placed in one course or the other based on their current practice setting. Even though the content of the two courses were similar, each one focused specifically on the more chronic or acute aspects of each disease, respectively. However, experience has shown that not all pharmacists fit neatly into one of those categories, such as home infusion pharmacists or those practicing in long term or subacute care. Perhaps more important is the fact that our graduates and those close to graduating have indicated very clearly that their attainment of the degree would be a stepping stone to a different practice venue altogether in pharmacy. Therefore, we will only offer one version of *Principles of Pharmaceutical Care* starting fall 1997, and all the entering students will take it, learning the entire spectrum of topics taught.

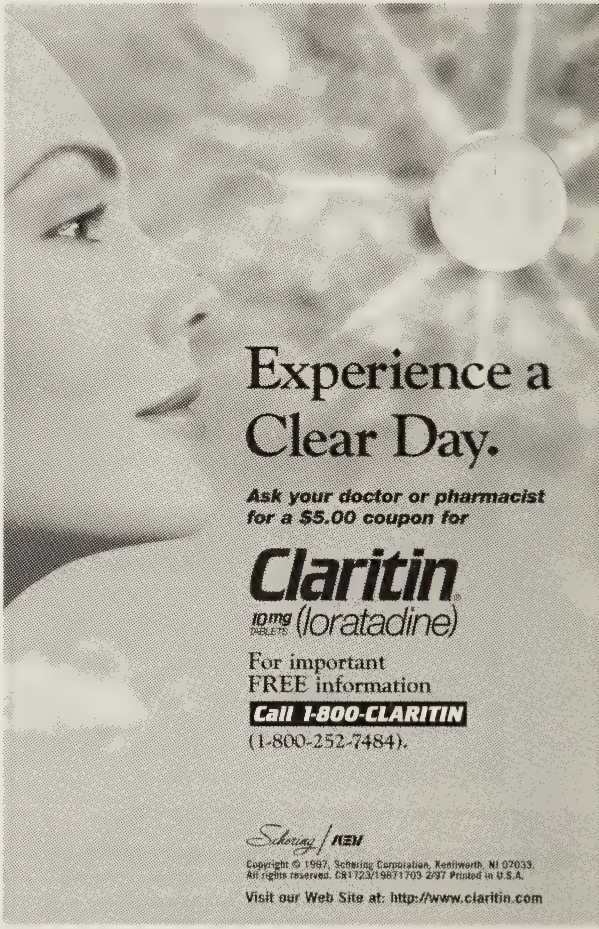
This line of thinking extended into the therapeutics area as well. As originally designed, students followed the *Principles* course with one of two therapeutics courses, either *Ambulatory Therapeutics* or *Acute Care Therapeutics*. Students again learned similar topics, but focused more on the chronic or acute aspects of each disease, respectively. For this reason, as well as a student demand for **more** therapeutics, the modified curriculum now requires students to take *Therapeutics I* **and** *Therapeutics II*, which will address both the chronic and acute aspects of diseases covered.

Experience over the past five years has shown that practitioners entering the Pathway have diverse backgrounds, and preparation in requisite knowledge is needed for subsequent success in the Pathway. Consequently, a new self-study course, *Readiness Assessment,* has been added to the curriculum to acquaint the student with, and assure minimum competency in, the anatomy, physiology, pathophysiology and pharmacology of disease states to be covered in the Therapeutics sequence of courses. Students work at their own pace in the completion of this requirement and may begin immediately upon acceptance to the Pathway.

Another new course added to the curriculum is the *Principles of Pharmaceutical Sciences*. This course will fulfill the required science component in the Pathway, and will address basic concepts in pharmaceutical sciences, and their application to pharmaceutical care. This first-year course will better enable the student to make the connection between basic science concepts and subsequent coursework, and ultimately their practice.

The last change was the decision to give students the opportunity to take elective courses. With the changes in coursework, some alteration in credit assignments to existing courses, as well as the decision to make the course *Prior Learning Assessment* an elective, students are now able to take four credits of didactic electives. This has been accomplished while still keeping the total number of credits required for degree completion to thirty. Some electives will be developed specifically for the NTPD Pathway, but students are welcome to register for any School elective for which they qualify.

The past five years of the Nontraditional Doctor of Pharmacy Pathway have been exciting ones. Almost forty practicing pharmacists have completed the Pathway. Their practices change. Enthusiasm continues to grow. The School is very proud of the graduates, and the pharmacists who continue in the Pathway; their commitment and feedback have helped us make a great program even better!



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Where do we go from here?

Pharmacy students look at life after graduation

Jon Gibson & Deborah Sharkey
University Of Maryland at Baltimore
School of Pharmacy
Pharm.D. Candidates

As students progress through the entry level Doctor of Pharmacy program at the University of Maryland School of Pharmacy, they are exposed to many different facets of the pharmacy profession. The curriculum has been structured in a way that provides students with insight as to the pharmacists' role in traditional as well as non-traditional practices. The experiential portion of the curriculum is spread out over the four years of the entry-level Pharm.D. program. During the first professional year, students participate in a panel discussion with pharmacists that practice in a wide range of settings. This panel discussion usually leaves the first year student with many ideas and questions about the direction of their career. Later in that year, a one-week distributive rotation in hospital and community pharmacy is also completed. The experiential component of the first-year is rounded out with a one-day experience in a non-traditional practice setting. The second and third years are spent working in a one-on-one relationship with a specific patient. This allows the student to refine their history-taking and physical assessment skills as well as providing the student with first hand knowledge of the various transitions a patient will experience with their health care. Clinical skills are gained during the third year and later put into practice as students complete distributive as well as clinical rotations. The experiential portion of the curriculum provides the student an opportunity to choose rotations in a variety of practice settings that may help them decide upon a particular area that they wish to pursue upon graduation.

In order to determine what pharmacy students envisioned they would be doing in the future, the Maryland Pharmacists Association compiled a survey and polled students from each of the four years of the UMAB School of Pharmacy. Students were asked for demographic data and about their future plans, previous education, motivations for future plans, and whether or not they would have entered a pharmacy program that offered a bachelor's degree if one were still offered. Only one response was accepted for each question except for the "motivation for future plans" question in which multiple responses were acceptable.

Responses to the survey seem to vary with respect to where the students are in the curriculum. For example, first and second year students have the most widely distributed responses to the question about their future plans. This most likely reflects the fact that they are constantly being exposed to new areas of pharmacy and that they are still exploring the many options that are available to them in these areas. In the third year, student response to the question "What are your plans for the future?" was overwhelmingly hospital or residency/future education. This may be a direct result of the third year students exposure to rotations and integrated science and therapeutics modules which are both clinical in nature.

The results of the survey show that the majority of respondents in the fourth year will be starting a career in community pharmacy and that they are motivated to do this by many factors including potential salary, job security, patient contact, and job satisfaction. The reason "other" was used predominantly by women who chose community practice as their future plan. The reason that was written in was flexibility in scheduling. Otherwise, the results were not different based on age or sex. Most students indicated that they would not enter a pharmacy program that offered a bachelors' degree if one was still offered. The fourth year class was the only class that had a majority of respondents indicate that they would have entered a B.S. program as opposed to the Pharm.D. program. Nearly two-thirds of the third year students who said they wanted to enter a residency program upon graduation also indicated that they would enter a bachelors' program in pharmacy. This probably indicates a lack of knowledge regarding residency programs as most, if not all, require applicants to possess a the Pharm.D. degree. When respondents were questioned further about their response to the B.S. versus Pharm.D. question, they indicated that they didn't think that a Pharm.D. was necessary for the practice of pharmacy, but that it would be necessary to be competitive among recently graduated pharmacists since all other schools of pharmacy are switching to an all Doctor of Pharmacy curriculum in the near future.

As students progress through pharmacy school, their goals and expectations evolve. This is expected as they are constantly exposed to new views and opportunities. It can be seen through the survey responses that the majority of students start school with a very idealistic attitude and leave with one that may be more realistic in today's ever-changing health care environment.

	First Year	**Second Year**	**Third Year**	**Fourth Year**
	N=67	N=75	N=64	N=66
Age				
< 21	7	0	0	0
21 - 25	36	43	34	26
26 - 30	19	18	19	27
31 - 35	4	9	6	8
36 - 40	1	3	5	3
41 >	0	2	0	2
Education				
No Degree	31	32	34	36
Bachelors	38	41	26	25
Masters	5	2	4	3
Doctorate	0	0	0	2
Sex				
Male	26	22	20	24
Female	43	53	44	42
Future Plans				
Community	23	35	14	40
Hospital	14	6	19	6
Industry	8	10	2	4
Long Term Care/Home Infusion	1	4	3	6
Residency/Further Education	15	8	18	7
Owner/Independent	3	3	0	0
Other/Unknown	5	9	8	3
Motivations				
Salary	22	36	34	26
Job Security	18	25	14	15
Patient Contact	17	19	25	16
Job Satisfaction	32	35	36	34
Other	0	2	9	3
B.S. Rx Program				
Yes	12	26	27	37
No	57	49	37	29

HEALTH NOTE

Provided by: The Nebraska Pharmacists Association

Hepatitis C: Facts and Figures

Hepatitis C is a liver disease that is caused by infection with the hepatitis C virus (HCV). Following are facts about this serious and frequently debilitating disease:

•***Prevalence***. An estimated 3.9 million Americans are infected with HCV, and up to 180,000 new cases are diagnosed each year.

• ***Symptoms***. Acute hepatitis C (initial infection) can cause flu-like symptoms such as loss of appetite, nausea, extreme fatigue, fever, and abdominal pain. As the disease becomes more severe, patients with hepatitis C may experience yellowing of the skin and eyes (jaundice). The majority of patients with acute hepatitis C have no symptoms, making early clinical detection of HCV infection difficult.

• ***Transmission***. It is believed that the virus is transmitted primarily through contact with infected human blood.

• ***Rick factors***. People who are at risk of contracting HCV include blood-transfusion recipients, dialysis patients, injection drug users, and those whose jobs expose them to human blood. People who undergo tattooing, body-piercing, or share infected personal-care items such as toothbrushes and razors also are at increased risk of contracting hepatitis C. In rare cases, infected pregnant women have been known to pass the virus to their fetuses. Transmission through sexual contact is likely, but has been difficult to prove. In up to 40% of reported hepatitis C cases, the exact mode of transmission is unknown.

• ***Long-term consequences***. In 50% to 80% of people with acute hepatitis C, the infection become chronic (persists for longer than six months). Approximately 10% to 20% of patients with chronic hepatitis C develop cirrhosis (scarring) of the liver or progressive liver failure. Hepatitis C also is associated with an increased risk of developing hepatocellular carcinoma, a type of liver cancer. At least 65% of patients with hepatocellular carcinoma have antibodies to the hepatitis C virus, indicating probable infection at some point in their lives.

• ***Testing***. The most commonly used tests are enzyme immunoassay antibody (EIA) blood tests, which detect antibodies to the hepatitis C virus. However, EIA tests often display a false-positive result, are not able to distinguish early (acute) infection from chronic, and cannot tell whether the infection has since resolved. Confirmation of HCV infection can be obtained with more specific supplemental tests, such as the recombinant immunoblot assay (RIBA-II). However, these tests do not provide insight into the replication of HCV, and may not detect the virus for several weeks after infection. The polymerase chain reaction, an investigational technique that amplifies genetic material in the virus, can distinguish between active and resolved infection, and can detect the virus within one to two weeks of infection.

•***Treatment***. Interferon alfa is the only established treatment for chronic hepatitis C. Studies also are under way to explore whether the antiviral agent ribavarin is effective in treating hepatitis C patients.

•***Prevention***. No vaccine is available to prevent HCV infection. Donated blood has been screened for HCV since 1990, decreasing the risk of contracting hepatitis C from blood transfusions to less than 1% by 1992. Prevention can be achieved by avoiding high-risk behaviors, such as illicit drug use, tattooing, and body-piercing. People who are diagnosed with hepatitis C should not donate blood, plasma, body organs, other tissue, or sperm. Additionally, hepatitis C patients should avoid sharing razors and toothbrushes, bandage open cuts and wounds, and use latex condoms during sexual intercourse.

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Volume XIV, No. 6

Patient Counseling on Topical Analgesic Therapy for Arthritis Pain, Part 1: Introduction

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and

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University of Cincinnati
Cincinnati, Ohio

Goals

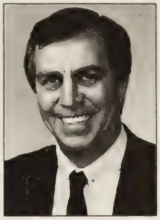
The goals of this lesson are to describe the basis for arthritis pain, and discuss topical therapy for its treatment.

Objectives

At the conclusion of this lesson, participants should be able to:

1. exhibit an understanding of the factors that predispose to development of arthritis;
2. choose from a list, mechanisms involved in the pain of arthritis;
3. select OTC products that can be used topically in the treatment of arthritis pain;
4. identify the pharmacologic and toxicologic actions, uses and misuses, and therapeutic application of drugs used in the topical treatment of arthritis pain; and,
5. choose from a list, specific advice to convey to patients about the treatment of arthritis pain with topically-applied products.

Gossel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According to the Arthritis Foundation, arthritis is a major cause of crippling disease. Affecting nearly 40 million Americans, more than one million new cases are diagnosed each year. It is reported that $35 billion is spent each year in health care costs and lost wages.

A variety of treatments are available that can modify arthritis pain and/or inflammation. There is currently no cure.

Even for conditions such as arthritis that can cause severe pain, patients may comply poorly due to side effects of their medication or because they forget to take a dose. For example, patients may use inadequate or excessive doses of medication. Arthritis pain also may not be managed adequately with systemic medication. Therefore, patients may turn to topical analgesic lotions and rubs to obtain relief with minimal adverse effects. Since these products are available without prescription, they can be obtained easily.

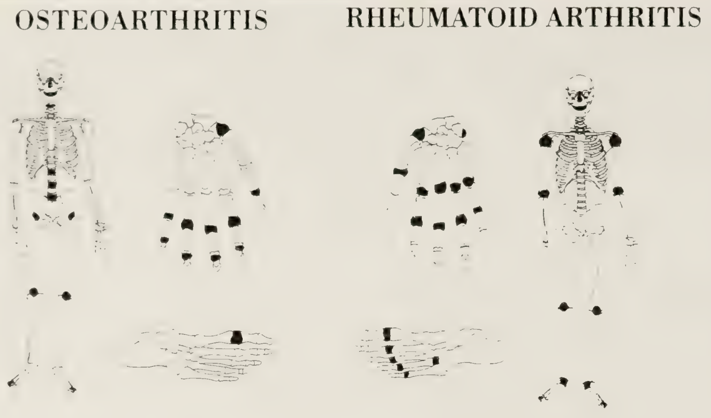
Pharmacists can be of major assistance in counseling patients with arthritis on the selection of appropriate topical products and proper use. Studies show repeatedly that when pharmacists take an active role in helping patients understand their disease process and the rationale for the prescribing of medication, compliance improves.

The physiologic mechanisms that cause arthritis pain, as well as drugs used topically to treat pain, are discussed in this lesson. Information to convey to arthritis patients to help them obtain maximal benefit from topical analgesic products is also included. The topic will be concluded in the second part of this two-part series.

Arthritis

The term *arthritis* (inflammation of a joint) refers to approximately 100 different inflammatory conditions that cause pain in joints and connective tissue. The most common forms are osteoarthritis and rheumatoid arthritis. Pain is a common complaint of both forms. It is important to briefly differentiate the two types.

Rheumatoid Arthritis. A chronic inflammatory autoimmune disease, rheumatoid arthritis


OSTEOARTHRITIS

RHEUMATOID ARTHRITIS

Sites of osteoarthritis

Sites of rheumatoid arthritis

Figure 1. Sites of osteoarthritis and rheumatoid arthritis development.

afflicts an estimated two million Americans. It usually begins between ages 20 and 45. Three females are afflicted for every male. Rheumatoid arthritis appears in multiple joints, especially the hands and feet (Figure 1).

Rheumatoid arthritis is characterized by inflammatory changes in the synovial membranes and joint structures with bone rarefaction (diminution in density and weight but not volume). Deformity of affected joints and tissue is common and can become extensive if the disease process is aggressive and is not treated properly.

Rheumatoid arthritis treatment goals include reduction of pain and inflammation. In addition, attention should be given to slowing the disease process with remission-inducing therapy. Rheumatoid arthritis patients must, therefore, receive medical attention and appropriate therapy.

Osteoarthritis. Osteoarthritis is a degenerative joint disease characterized by deterioration of the articular cartilage, bone hypertrophy at the margins, and changes in the synovial membrane. It is sometimes described as "wear-and-tear arthritis." Most osteoarthritis is noninflammatory, with loss of cartilage as the primary cause of disability. In 10 to 20 percent of osteoarthritis cases, swelling follows fragments of diseased cartilage that collect in the synovial space. Common sites of involvement are shown in Figure 1. Unlike rheumatoid arthritis, osteoarthritis is not a systemic disease.

The incidence of osteoarthritis increases with age. As many as 80 percent of the population is reported in some studies to experience it by age 65. Osteoarthritis may also appear in younger individuals following joint injuries, such as those sustained in football and other contact sports, or as a result of a hereditary disorder.

The treatment of osteoarthritis includes reducing pain and minimizing further joint damage.

Causes of Joint Pain and Inflammation

Tissue destruction and/or joint inflammation are complicated processes that may be initiated by a large variety of chemical mediators. These include interleukin-1 (IL-1), IL-6 and IL-8, leukemia inhibitory factor (LIF), monocyte chemotactic protein (MCP)-1, and prostaglandins (e.g., PGE_2). Protease enzymes hasten tissue destruction. Neuropeptides, such as substance P, mediate neural effects on inflammation and connective tissue metabolism.

Substance P contributes significantly to the pain and inflammation of arthritis. This neuropeptide is found in unmyelinated fibers (type C) that innervate ligaments, tendons, joint capsules, and blood vessels in the synovium and in bone. These sensory nerves transmit pain signals upon exposure to noxious stimuli.

When tissue is damaged, the neurons fire, releasing substance P at nerve endings (in the skin or joint) and at synapses within the spinal cord. The nociceptor (a receptor which is stimulated by injury; a receptor for pain) message is sent to the brain and pain is felt.

Besides playing a major role in pain perception, substance P has pro-inflammatory functions. Substance P increases proliferation of synovial cells (synoviocytes), which can lead to excessive development of synovial tissue over the joint surface (pannus formation) and joint destruction in rheumatoid arthritis. Substance P stimulates synoviocytes to release PGE_2, which promotes inflammation, and collagenase which stimulates cartilage destruction. Macrophages from inflamed joints have been shown to synthesize and secrete interleukin-1 and TNF-alpha in the presence of substance P. Convincing experimental evidence that substance P is an important contributor to arthritis pain is summarized in Table 1.

The causes of arthritis are numerous. Of paramount significance is that, regardless of its cause, pain is the symptom for which most patients with arthritis seek relief.

Table 1
Evidence for a Role of Substance P in Arthritis Pain

- There is an alteration in the innervation of joints of rheumatoid arthritis patients by substance P-containing neurons.
- Injecting substance P into joints in animals increases soft tissue swelling, decreases bone density, and increases joint space narrowing.
- Substance P levels in synovial fluid of joints afflicted with either osteoarthritis or rheumatoid arthritis are higher than plasma levels.

Treatment of Osteoarthritis Pain

Oral Medications. The most frequently used form of arthritis therapy is the nonsteroidal anti-inflammatory drugs (NSAIDs). Approximately 1 to 2 percent of Americans are believed to use NSAIDs regularly; many more, however, use them intermittently.

Effective analgesics in low-to-moderate doses and anti-inflammatory in larger doses, NSAIDs are not suitable for all persons. They can incite a number of adverse effects and can be toxic if misused. It has been estimated conservatively that between 2 and 4 percent of patients who take NSAIDs longer than two months experience potentially serious adverse reactions. Many of these people are elderly, and toxicity can be increased when they are on multiple drug therapy.

Besides using oral NSAIDs for treatment of osteoarthritis, physicians will prescribe other analgesics occasionally such as acetaminophen, or intra-articular corticosteroids. In addition, patients may self-medicate with OTC systemic analgesic products. Their reasons for doing so are often related to financial considerations, including health insurance limitations. Many, though, do not wish to take the large or frequent doses of medication that may be necessary with OTC agents to treat their condition effectively.

Nonpharmacologic Approaches. Nonpharmacologic approaches to therapy include rest, application of heat and cold, physical therapy, and altering patients' lifestyle and work activity. These measures help relieve pain, and some may also delay further damage to affected joints.

The mechanism of action from heat and/or cold massage on joint and skeletal pain is not understood entirely. Several theories of how these may act to relieve pain have been proposed. Most likely, heat produces analgesia by elevating the pain threshold of peripheral nerve fibers. Cold may decrease the swelling that causes pain by minimizing vasodilation associated with inflammation. Ice or cold packs can be applied to the painful site for approximately 20 minutes and then removed. Leaving them in place for longer periods is not recommended.

For minor pain, heat can be applied with a heating pad or moist heat pack. Moist heat is considered the most effective method of application since moisture enhances the penetration of heat into joints and muscles.

Muscle pain can be managed with deep heat (thermotherapy, diathermy). This helps decrease muscle pain because it promotes restoration of elasticity to collagen. The most abundant protein in humans, collagen is a basic building constituent of tendons, ligaments and muscles. Collagen stretches like a coil and normally recoils to its natural length with normal movement. If injured by excessive stretching or injury, it may not return to its previous length, thus causing discomfort.

Heat and massage increase the flow of blood and lymph in the skin and underlying structures. This enhances delivery of oxygen and nutrients and removal of metabolic waste products. Heat can exert muscle relaxant and counterirritant activities.

Exercise is an important component of arthritis therapy to increase and maintain mobility and minimize pain. Controlled, purposeful exercise can increase the strength of muscles and other supporting tissues around a joint to promote greater range of motion.

Topical Analgesics

Externally-applied analgesics relieve the pain of musculoskeletal origin including arthritis. Topical therapy for arthritis has been used widely for centuries. Only recently has there been a scientific basis for some of these approaches. Discussion in this lesson and the next will be limited to ingredients in OTC products that soothe the aches and pain of arthritis, as well as provide analgesic relief to sore muscles, tendons, ligaments and bursae. Pharmacologic agents such as local anesthetics and skin protectants, which are also classed as external analgesics, will not be included.

Counterirritants. Inducing mild pain or other neural sensation voluntarily as a means to counter a more intense one is instinctive. For example, pain sufferers may bite their lips, clench their fists, massage their skin or dig their nails into their skin in order to reduce perception of more intense pain. Counterirritant drugs are applied to the site of pain for the same purpose. They are made up of a wide variety of chemical classes.

The therapeutic objective of counterirritant use is to provide analgesic relief to an area of the body by creating an alternative nociceptive response to pain. Counterirritants achieve this by producing mild, localized inflammatory reactions. The intensity of response is dependent upon the specific counterirritant and its concentration, the vehicle used, and the extent of contact with the skin. Mere massaging of the skin during product application can help suppress pain transmission.

Table 2
Classification of OTC Counterirritant External Analgesics

	Group Characteristics	Ingredients	Concentrations
A	Induce redness and irritation; more potent than other commonly used counterirritants	allyl isothiocyanate	0.5-5%
		ammonia water	1-2.5%
		methyl salicylate	10-60%
		turpentine oil	6-50%
B	Produce cooling sensation; possess strong organoleptic properties	camphor	3-11%
		menthol	1.25-16%
C	Cause vasodilation	histamine dihydrochloride	0.025-0.1%
		methyl nicotinate	0.25-1%
D	Incite irritation without rubefaction; equal in potency to Group A	capsicum	0.025-0.25%*
		capsicum oleoresin	0.025-0.25%*
		capsaicin	0.025-0.25%*

*containing capsaicin ingredients
Ref: *Federal Register* 44(234), 1979; 48(27), 1983

Some counterirritants may exert their "analgesic" action because of their pleasant (aromatic) odor that strongly suggests medical effectiveness. In other words, they smell "mediciney."

Although several theories have been advanced to explain the pharmacologic action of counterirritants, there is no unanimity of opinion. The *summation of pain stimuli* is one theory that has been proposed. It is based on the belief that counterirritants stimulate several receptors in the skin by inducing chemical signs of inflammation (i.e., heat, erythema and swelling). This mild stimulation obscures the painful stimuli that originates elsewhere in the affected joint or muscle. Counter-irritation has been likened to the physiologic effects that are achieved with acupressure or acupuncture.

The summation of pain stimuli theory is supported by neuroanatomy and physiology factors. Stimuli emanating in skeletal muscle are conducted along nerve fibers in a common pathway with impulses from the skin. Both impulses converge in the same area of the spinal cord for transmission to the brain. By increasing the amount of dermal sensation, the individual's perception of joint or muscle pain can be decreased.

Some drugs possess rubefacient action in addition to counterirritant properties. This means they incite active vasodilation of the cutaneous vasculature, which brings more blood into the area. This, in turn, increases the skin temperature to result in a feeling of warmth and comfort.

Counterirritants that have met FDA's therapeutic criteria for safety and efficacy and are, therefore, available in OTC external analgesic products are listed in Table 2. They are grouped into four chemical and/or pharmacologic categories that provide qualitatively different types and/or extent of irritation.

Group A drugs include the more potent counterirritants. These are strong irritants that cause erythema (redness) and warmth at the site of application. Group B counterirritants provide cooling and/or warmth and a tingling sensation to the skin. Their response, overall, may be due partly to their soothing medicinal odors.

Group C substances are vasodilators. Group D contains capsicum, capsicum oleoresin, and capsaicin. These substances reportedly provide counterirritant activity that can be as great as those in Group A, but without rubefacient properties.

Methyl Salicylate. Methyl salicylate is categorized in Group A of the counterirritant external analgesics. It occurs naturally as wintergreen oil or sweet birch oil. Synthetic methyl salicylate, the usual form in commerce, is prepared by the esterification of salicylic acid with methanol. It combines counterirritant action with prostaglandin inhibiting activity of salicylate. Very low concentrations of methyl salicylate have been used in candy, chewing gum, and other confections, due to its pleasant aroma and flavor.

Methyl salicylate has been the most commonly used counterirritant for the temporary relief of pain. The recommended topical dosage is a 10 to 60 percent concentration applied three to four times a day. It penetrates intact skin readily after topical application. There is evidence to suggest that sufficient amounts of methyl salicylate can be absorbed percutaneously to result in systemic analgesic activity. Because of this possibility, methyl salicylate should be used with caution in individuals who are sensitive to aspirin or who suffer from asthma or nasal polyps.

Patients should be told to avoid the use of heating pads or packs concurrently with methyl salicylate, or external analgesics in general, and to not apply them after strenuous exercise, especially during hot and humid weather. These conditions can magnify the extent of systemic drug absorption, and in the case of methyl salicylate have resulted in reports of severe adverse reactions. Methyl salicylate exhibits a safety profile similar to other salicylates.

Menthol. Menthol is a representative compound from Group B. It is a flavoring agent in a number

Table 3
Patient Counseling on the Use of External Analgesics

- Wash your hands before applying this product.
- Cleanse the area of the skin to which the product will be applied with soap and water each time you are ready to apply the medicine, unless otherwise directed by your doctor.
- Apply a generous amount of product to the area, rub it in well, and massage the area for several minutes.
- Wash your hands after applying the medicine.
- Keep the medicine away from your eyes, mouth, broken or damaged skin, open wounds, cuts or scratches.
- Do not bandage the area unless you were directed to do so by your doctor.
- Do not use this medicine more frequently or in larger quantities than suggested by your doctor or pharmacist.
- If skin irritation develops, pain lasts longer than 10 days or redness is present, contact your doctor.
- Do not use this medicine on children under 12 years of age, unless directed by your doctor. Keep all medicines out of the reach of children. Read all labels before using this medicine.
- In case of accidental ingestion, call your doctor or poison control center immediately.

of products that are taken internally when used in small quantity. For example, candy, chewing gum, cigarettes and cough drops may contain menthol flavoring. Inhaled menthol has also been used as a nasal decongestant.

In concentrations of 0.1 to 1 percent, menthol is used as an antipruritic agent. In higher concentrations (1.25 to 16 percent), menthol exerts counterirritant properties, in some cases merely replacing one sensation for another. When applied to the skin, menthol stimulates the neurons sensitive to cold while depressing nociceptive neurons.

Counterirritant concentrations of menthol applied topically produce a sense of coolness followed by a feeling of warmth. The sensation of cold is not due to actual cooling of the skin; menthol induces vasodilation, and the skin temperature at the site is actually warmer than other parts of the body. The counterirritant action of menthol differs, therefore, with the vehicle employed and the method of application.

Menthol can be used alone as an external analgesic. It is also combined with other ingredients such as camphor that have antipruritic or analgesic properties. Eucalyptus, thymol and other aromatic oils are added for their medicinal smell.

Methyl Nicotinate. Categorized as a Group C counterirritant, methyl nicotinate is applied three to four times per day in concentrations of 0.25 to 1 percent. It is a safe and effective counterirritant. Though nicotinic acid is inactive topically, esterification causes a marked increase in skin penetrability.

Vasodilation, erythema and an increase in skin temperature occur with topical application of methyl nicotinate. Changing the concentration does not change the rate of absorption, but does increase the intensity of the reaction.

The vasodilatory action of methyl nicotinate can be blocked, at least in part, by prior application of ibuprofen or other NSAIDs, indicating that methyl nicotinate may induce vasodilation secondary to an increase in prostaglandin synthesis. When methyl nicotinate is applied over large body surface areas, generalized vasodilation can occur, and some individuals have experienced marked reductions in blood pressure, and syncope has developed as a result.

Counseling Patients on Topical Analgesics

Information to pass along to patients using topical analgesics is presented in Table 3. The topic of counseling arthritis patients on these products, including capsaicin, will be continued in Part 2 of this lesson series.

Money Minute

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Think Globally -- Investment Opportunities Lie Overseas

Ford builds cars in Mexico, and McDonald's sells Big Macs in Tokyo. Likewise, foreign companies manufacture and sell their products in the United States. Factor in the Internet and other global communications networks, and you can virtually see the world getting smaller.

Investing is going global, too. Bill Westhoff, senior vice president of international investments for American Express Financial Advisors, provides his outlook on investing outside the United States.

Why should investors consider foreign stocks? They offer additional investment and diversification opportunities. Though past performance is not indicative of future results, foreign markets have historically offered higher returns than the U.S. market.

Why is overseas diversification important? Investing in *global or international funds* may be one way to offset negative performance in one country with a positive return elsewhere. In 1995, overseas markets were up about 11 percent, but the U.S. market climbed about 37 percent.

What is your outlook on emerging markets? Developing countries such as Argentina and Thailand are rapidly growing markets that offer investment opportunities. However, these emerging markets can be volatile. There are always special risks associated with international investing. Most emerging markets performed poorly last year, but many are recovering.

How do foreign currencies come into play? When investing globally, it's wise to engage in *currency hedging* to account for fluctuating currency values. Here's an example. Investing in a German stock, you're converting the stock's value to U.S. dollars from deutsche marks. Even if the stock remains stable, the investment can appreciate if the deutsche mark appreciates relative to the dollar (if it takes fewer deutsche marks to buy $ 1). It can work the other way, too. If the foreign currency depreciates relative to the dollar, that reduces your return. The relative values of currencies go up and down over time.

Financial Glossary: *Highlighted terms defined below.*

Currency hedging -- Guarding against losses -- or seeking gains -- in foreign investments due to fluctuating currency values. For U.S. investors in foreign securities, the value of the U.S. dollar relative to other currencies may be as important as the investment's performance. Say you invest in a Japanese stock, which requires converting the stock's value to dollars from yen. If the yen "weakens" (so it takes more yen to equal a dollar), than your return declines. A "stronger" yen boosts the stock's return.

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Continuing Education Quiz

May / June 1997

This month's questions are taken from the article on "Patient Counseling on Topical Analgesic Therapy for Arthritis Pain, Part 1: Introduction". Circle your answers to the following questions and mail the entire page to *Maryland Pharmacist CE*, 650 West Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members $ 10.00). The completed quiz for this issue must be received by 6/15/99. A continuing education certificate for one contact hour (one credit) will be mailed to you within six to eight weeks. Please type or print clearly. ACPE# 129-144-96-006-H01

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1. Which of the following statements about rheumatoid arthritis is true?
   a. It is a chronic inflammatory autoimmune disease.
   b. It occurs in males to greater extent than in females.
   c. It occurs in only one joint at a time.
   d. It usually begins around the age of 50.

2. Which of the following is the chemical mediator that initiates tissue destruction and joint inflammation?
   a. Intrinsic factor
   b. Interleukins
   c. Interferons
   d. Intermoogliabop

3. Which of the following is most appropriate to tell a patient using an external analgesic?
   a. Apply a small amount, about the size of a dime.
   b. Do not rub the area after applying the medicine.
   c. Cover the area with an occlusive dressing to help penetration.
   d. Do not apply the medicine to broken or damaged skin.

4. The deformity caused by rheumatoid arthritis results in which of the following bone changes?
   a. Resorption
   b. Osteoporosis
   c. Rarefaction
   d. Osteomalacia

5. The condition referred to in question #4 results in diminution of all of the following EXCEPT:
   a. density.
   b. volume.
   c. weight.

6. The neuropeptide that mediates neural effects on inflammation and connective tissue metabolism is:
   a. substance A.   c. substance G.
   b. substance D.   d. substance P.

7. The term *diatherapy* refers to the application of:
   a. cold.   c. heat.
   b. drugs.   d. water.

8. Osteoarthritis is characterized by all of the following EXCEPT:
   a. deterioration of articular cartilage.
   b. bone hypertrophy at the margins.
   c. changes in the synovial membrane.
   d. severe systemic inflammation.

9. Methyl salicylate is a member of which of the following counterirritant external analgesic groups?
   a. Group A   c. Group C
   b. Group B   d. Group D

10. The group of counterirritant external analgesics referred to in question #9 exerts which of the following activities?
   a. Redness only
   b. Irritation only
   c. Both redness and irritation
   d. Neither redness nor irritation

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Every two years, each DEA registrant is required by both state and federal law to conduct a complete inventory of all controlled substances in their possession on May 1. Depending on when the DEA license was obtained, your inventory may be required on odd years or on even years. To help its members to comply with the law, MPhA has created the publication, ***"The Controlled Substance Inventory"***.

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Robert J. Boerner

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Changing for the Future

Jean Freels, President

First allow me to introduce myself. I am Jean Freels, a pharmacy manager for Weis Markets. I face the same situations and share the same frustrations that I'm sure most pharmacists face on a daily basis. I am confident however, that through a strong professional association, we can affect positive change within our profession. There is no one else looking out for your interests professionally. You may have an employer or other organization that provides you with C.E., technical support, or other basic pharmacy information, but it is MPhA that consistently monitors issues that affect you professionally. MPhA is *our* collective voice. MPhA interacts with various groups such as the Board of Pharmacy, the School of Pharmacy; the legislature, as well as other pharmacy associations and organizations. It is through this representation we can change our profession to meet the needs of the future.

As the profession of pharmacy changes, MPhA is also changing. Two years ago at our Mid-Year meeting, we presented our long term goals and reaffirmed the direction of the association. MPhA is also looking to build new alliances with affiliated groups. However, MPhA has limited resources and needs to allocate them judiciously based on the needs of its membership. (As determined through surveys, and both written and verbal feedback). To accomplish this goal, MPhA needs input and involvement from its membership.

I would like to elaborate briefly on some of the changes within our association that will occur this year. The dues structure has been re-evaluated to ensure equality. The category of owner/manager will no longer carry a greater financial burden than other categories of pharmacists. Our goal is to continue to strengthen MPhA as a professional association of *pharmacists,* not *pharmacies* in which all practice settings are represented. Other changes taking place this year include a format change of both the Mid-Year meeting as well as the convention. The Mid-Year meeting will be expanded to a two day event. In addition to components of previous years meetings, the Mid-Year will now include a trade show. The convention schedule will include a weekend (Saturday afternoon through Tuesday morning) and will not interfere with Father's Day. Hopefully, these changes will allow more members to participate.

Lastly, as a result of the changes in Title 12 contained in House Bill 1229, the Board of Pharmacy will have a new nomination process in which MPhA will participate. Through the internal changes described above and this sort of external activity MPhA will strive to provide pharmacists with whatever support they need to facilitate the progression of pharmacy into the next millennium.

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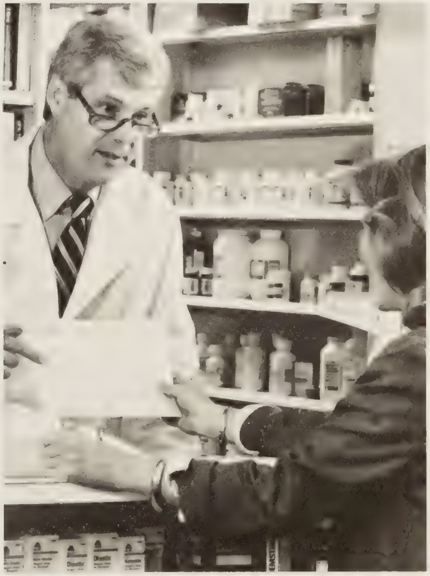

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Directors Column

Southeastern States Pharmacy Association Officers 27th Annual Conference

Robert J. Boerner
Executive Director

I am told that the Executive Director typically writes an article for each issue of the journal. I pointed out that I had already authored the "Introduction to the New Executive Director" for the Newsletter and suggested that should be enough punishment both for me and for the readers of these publications. However, journalistic tradition is not to be denied as you can see.

This situation is a little, or more accurately a lot, like the blind leading, not the blind, but the sighted. It is too early for me (I am six weeks old in pharmacy at this writing) to have enough experience with the Association to write about very much that would inform the readership. So I am left with two apparent choices, write more about myself or write something I, as yet, know little about.

In my short tenure the one thing I can report on the Southeastern States Pharmacy Association Officers 27th Annual Conference in Charleston, South Carolina August 22-24. I found that session very informative. Jim Tristani came along as my mentor and to provide the continuity and historic perspective that I obviously lacked. State executives from all the Southeastern members except Kentucky participated. Sixty-two people were involved including the sizable host contingent of 21 from South Carolina and the next largest group of nine from Georgia which has a permanent staff of 38. (They struggle along with only 24 directly involved in the ongoing administration of the association, however.) Jim and I were not the smallest delegation. Louisiana and Florida had only one representative each.

Most of the agenda involved information sharing with legislative and regulatory issues predominating. The status of pharmacy collaborative practice acts was the main topic of discussion. Maryland's situation is fairly typical with basic legislation passed, but full collaborative practice still pending. The advice of several states was that the term "protocol" was generally better understood and received by physicians than "collaborative practice." A number of states observed that while, when initially approached, physicians voiced no opposition to this legislation, once it was introduced they became very vocally opposed. We need your help to ensure that the Maryland Legislature passes appropriate legislation this session. Please contact the MPhA office if you are willing to become involved.

Programs addressing the needs of "employed" pharmacists was another major topic. Strategies such as town hall meetings on work life issues, surveys to learn what services would be of use and separate sections or academies were the principal avenues followed to provide for this class of membership. Most states had tried at least one of these tactics. One had all of the employed pharmacists as members, and two had not done anything to provide for them. MPhA is very interested in your ideas about what we could do to serve these pharmacists.

Convention dates, schedules and formats were also discussed. Most states hold their conventions in either June or July. South Carolina chose late May. Exhibits were generally done in the summer, but one or two had them at midyear. Child care and/or entertainment was provided by most states. South Carolina had a function which involved legislators and students. It began with a general reception and later moved into regional discussions or caucuses.

All in all it was a very interesting two days. The South Carolina weather in August even cooperated with low humidity and temperatures in the 80's.

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Speaker Crystal King called the second business session of the House of Delegates to order. House Secretary Tracy Baroni conducted a role call. Forty-eight delegates were present.

Installation of Officers and Trustees

Speaker King announced the election results of the May 1997 MPhA elections. According to those election results: persons elected as *Trustees* include Crystal King, Matthew Shimoda, Leo Mallard, and Paul Holly. Officers for the 1997-1998 year are as follows: Joseph Marrocco - *Vice President*; Lance Berkowitz - *Treasurer*; Gerard Herpel - *President-Elect*; and Jean Freels - *President*. Mary Benson is the *President of ASP*. The Canvassing Committee reported that the House had elected Joseph DeMino as *Speaker* and Rhea Marie del Rosario as *Vice-Speaker*. Past President Davidov conducted the installation ceremony for the new trustees and officers.

Resolutions Adopted by MPhA's House of Delegates

Vice-Speaker and House Resolutions Committee Chairman Joseph DeMino announced that the House Resolutions Committee had received six member-submitted resolutions for consideration by the Committee prior to the House session.

Pharmacist Continued Competence

Whereas, pharmacists who practice in Maryland are required to take and pass the NABPLEX prior to practicing; and,

Whereas, pharmacists licensed to practice in Maryland are required to obtain 30 credit hours of continuing education every two years in order to renew their licenses; and,

Whereas, no other licensed professional practicing in Maryland is required to take a continued competence assessment mechanism to maintain a professional license;

Therefore, be it resolved that the Maryland Pharmacists Association opposes the institution of a continued competence assessment mechanism requirement by the Maryland State Board of Pharmacy.

The Maryland Pharmacists Association opposes the institution of a continued competence assessment mechanism requirement by the Maryland State Board of Pharmacy.

Collaborative Practice Agreements

Whereas, collaborative practice agreements between pharmacists and other health care professional are designed to optimize patient outcomes; and,

Whereas, pharmacists are educated both formally and through practical experience to initiate, monitor, and modify drug therapy to enhance patient outcomes; and,

Whereas, numerous pharmacists throughout Maryland are currently working in collaborative practice arrangements to the benefit of patients;

Therefore, be it resolved that the Maryland Pharmacists Association supports the passage of legislation authorizing pharmacists to enter into collaborative practice agreements.

The Maryland Pharmacists Association supports the passage of legislation authorizing pharmacists to enter into collaborative practice agreements; and supports the passage of legislation or regulation authorizing appropriately educated pharmacists to administer drugs.

Administration as the Practice of Pharmacy

Whereas, community pharmacists are the most accessible health care professional by virtue of the nature of the practice setting; and,

Whereas, pharmacy students are currently educated both formally and through practical experience to administer drugs, including vaccines; and,

Whereas, there are numerous certification courses and ACPE-approved courses to educate licensed pharmacists on the administration of vaccines;

Therefore, be it resolved that the Maryland Pharmacists Association will assist pharmacists in acquiring appropriate education to administer drugs, including vaccines; and,

Be it further resolved that the Maryland Pharmacists Association supports the passage of legislation authorizing pharmacists to enter into collaborative practice agreements.

The Maryland Pharmacists Association will assist pharmacists in acquiring appropriate education to administer drugs, including vaccines; and, supports the passage of legislation authorizing pharmacists to enter into collaborative practice agreements.

The continued success of the Maryland Pharmacists Associations efforts to provide programs, events and continuing education to pharmacists is directly attributable to companies, organizations and individuals which generously provide various support services and financial contributions. We want to express our sincerest thanks to all who participated in the 115th Annual Convention.

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Montgomery County Pharmacists Association
Novo Nordisk Pharmaceuticals
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Senior Pharmacists Association
SmithKline Beecham
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There were 207 registered participants and 43 exhibitors at this year's convention.

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Promises, Promises

Remarks to the House of Delegates,
Maryland Pharmacists Association
June 16, 1997

David A. Knapp, Dean
School of Pharmacy

I was introduced to this House of Delegates six years ago as the new dean of the University of Maryland School of Pharmacy, scarcely a month after I was appointed. I received a warm welcome from the delegates -- a honeymoon period that lasted about four minutes! We then proceeded with a scheduled debate about the merits of the School's planned new educational program. Our faculty had the audacity to throw out an excellent baccalaureate program, dismantle a superb two-year post-baccalaureate Pharm.D. program, and embark on building a new entry level four-year professional Doctor of Pharmacy program from scratch. Only in this way, we felt, would we be able to construct a curriculum that would prepare pharmacists for the revolution in health care delivery that was poking its nose over the horizon. Only in this way, could we help our students learn the problem-solving skills, develop the critical thinking methods, and demonstrate the communication abilities that would be required for the 21st century.

Not everyone in that room agreed that our approach was the only way! Arguments were expressed with intelligence, logic, concern, passion, and vehemence. Out of the crucible of that debate, and the many others that followed it, came a much stronger program, one that has helped to propel the School of Pharmacy to a ranking among the top ten schools of pharmacy in the nation.

Also flowing from the debates was a series of promises that I made about the conditions under which we would move to our new curriculum.

Promise #1. We would maintain our class size at 100. We would not reduce our class size as a result of going to the Pharm.D. program. Critics believed that the increase in tuition required coupled with the increase length in the curriculum would depress enrollment. The market, however, has responded favorably to the new program. The applicant pool for the baccalaureate program hovered at 400 in the last years of the baccalaureate program. It jumped to 700 for the first year of the new program and has remained high. We continue to admit about 100 students to our entering class. Despite increases in our tuition and fees, the cost of Maryland pharmaceutical education remains cheaper than day care! Promise #1 has been fulfilled.

Promise #2. We would not have a year with no graduates when we went from the 3-year baccalaureate to the 4-year doctor of pharmacy program. Indeed, through an unusual transition curriculum, we offered the opportunity for a limited number of practicing pharmacists to come back to school for two years to earn their doctor of pharmacy degree. Thus, for two years we graduated about 70 pharmacists a year and are now back to 100. Promise #2 has been fulfilled.

Promise #3 was a commitment to develop a nontraditional pathway for baccalaureate practitioners to earn the doctor of pharmacy degree if they desired. That program has been developed and enrolls well over 200 students and has produced about 40 graduates. Promise #3 has been fulfilled.

Promise #4. An expanded experiential program. The number of clerkship and externship hours has increased from 1,000 to 1,600 hours. It is now directed by Richard Rumrill who joined our staff last year. Promise #4 has been fulfilled.

Our first class in the new curriculum graduated in May. Our new curriculum is in place and we have a continuing commitment to improve it. In June, I joined a team of five of our faculty at the second annual American Association of Colleges of Pharmacy Institute on Professional Education. We joined faculty from 23 other schools of pharmacy nationwide to spend five days in a discussion on how to further improve our curriculum and our teaching. We continue to work to make sure that our program is one of the finest in the nation.

Teaching and research are not mutually exclusive. At the same time the School was developing its new educational programs, the faculty was expanding their research and scholarly contributions. External funding for the School's programs has grown from about $1 million to over $8.4 million last year.

Cooperative efforts assisted by the Maryland Pharmacists Association have led to an additional $440,000 annual in operating funds for the Maryland Poison Center. Although we are still some $350,000 short of an optimum budget for Maryland Poison Center, this increase goes a long way to helping the Maryland Poison Center meet its statewide commitments.

Two new senior faculty members will join the School in mid-July. The first is Dr. Gary Smith, Professor of Pharmacy Practice at the University of Arizona who will take over as chairman of the Department of Pharmacy Practice and Science. Second is Dr. Bruce Stuart, Professor of Health Economics at Penn State University who has been appointed to the Parke-Davis Chair in Geriatrics.

Earlier this spring, a new corporation named University Pharmaceuticals of Maryland, Inc. was formed. This for-profit company will provide pharmaceutical development and research services to clients in the pharmaceutical industry. In addition, it will provide scientific and technical education programs. The company is organized to work in cooperation with the faculty of the School of Pharmacy with profits used to support School of Pharmacy programs. This unusual private sector effort has been made possible by the passage of the Public/Private Partnership Act by the Maryland legislature in the spring, 1996.

The School of Pharmacy is pleased to be a part of the effort that resulted in the passage of major revisions in the Pharmacy Practice Act by the Maryland General Assembly this spring. Although initiatives in collaborative practice and drug administration privileges for pharmacists were not addressed by the legislation, the revisions did serve to update the Act in many important ways. The Task Force on the Future of Pharmacy will continue its work this summer to address issues of collaboration and drug administration.

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ANNUAL REPORT

THE MARYLAND STATE BOARD OF PHARMACY
1996-1997

In compliance with the provisions as set forth in the Health Occupations Article Section 12-205 of the Annotated Code of Maryland, this report is submitted to the Honorable Parris N. Glendening, Governor of Maryland, the Secretary of the Department of Health and Mental Hygiene, Martin P. Wasserman M.D., J.D. and to the Maryland Pharmacists Association. This is the ninety-third report to the Governor and Secretary and the fourteenth report to the Association. The report covers the activities of the Maryland Board of Pharmacy for the period May 1, 1996 to April 30, 1997. This report is also being submitted to the McKeldin Library of the University of Maryland, the Enoch Pratt Free Library, the Department of Legislative Reference, the Hall of Records and the State Library.

Meetings
During the year the Board held twelve Board meetings to discuss all issues relevant to the pharmacy profession.

Officers and Members
The Board consists of the following officers and commissioners: George Voxakis, President; Dorothy Levi, Secretary; Stanton Ades, Wayne Dyke, Barbara J. Faltz Jackson, Rev. William Johnson, Sr., W. Irving Lottier, and David Russo, Commissioners. All of the officers and commissioners are registered pharmacists in the State of Maryland with the exception of Ms. Jackson and Rev. Johnson, who are consumer (public) members of the Board.

Personnel
The staff consists of Norene Pease, Executive Director, David Denoyer, Pharmacist Compliance Officer, Tamarra Banks, Network Specialist, Monique Cheatham, Secretary to the Executive Director, David Oliver, Secretary to the Pharmacist Compliance Officer, Carol Gibbs, Licensing Secretary, and Doris Thomas, Fiscal Aide.

Examination
The Board conducted examinations for licensure of pharmacists twice during the year. The examinations were held at the University of Maryland School of Pharmacy on June 25, 26, and 27 1996 and at the University of Maryland School of Social Work on September 17 and 18, 1996.

The applicants who were examined in June of 1996 were licensed in August, 1996. There were one hundred ninety-two applicants for the Board examination in June 1996. One hundred forty-eight passed both the theoretical and practical portions of the examination and were licensed. Forty-four candidates failed the examination.

There were fifty-three applicants for the Board examination in September, 1996 (F.Y. 1997). Forty- one passed both the theoretical and practical portions of the examination and were licensed. Twelve candidates failed the examination.

Data relative to the June 1997 examination will be given in the next Annual Report.

The pharmacist licensure examination is given in three parts consisting of the following:

Part I - NABPLEX
Part II - Pharmacy Law
Part III - Laboratory

The NABPLEX is obtained from the National Association of Boards of Pharmacy. The Pharmacy Law Exam and the Laboratory Exam are compiled by members of the Board. The pharmacy law examination requires examinees to respond according to what a pharmacist practicing in Maryland must do in a particular situation in order to comply with Maryland and Federal law. The Laboratory Examination requires each candidate to compound and label four prescriptions per applicant.

Each of the three parts stands on its own for grading purposes. An examinee need only retake the section(s) failed. The passing grade for each section is 75 percent.

The following table shows the number of pharmacists who were licensed by examination during the past ten years.

Year	*No. of Pharmacists*
1984-1985	92
1985-1986	109
1986-1987	105
1987-1988	121
1988-1989	135
1989-1990	167
1990-1991	156
1991-1992	149
1992-1993	145
1993-1994	199
1994-1995	199
1995-1996	165
1996-1997	181

As in the past, many pharmacists applied for reciprocal licensure in Maryland in order to accept positions with employers or in order to become self-employed as pharmacists in Maryland.

In all cases, an applicant for reciprocal licensure must appear for a personal interview. The entire Board must act on whether or not to grant licensure to such applicants, who must sign an agreement to comply with Maryland's laws pertaining to drugs and pharmacy.

The following table shows the number of pharmacists granted Maryland licensure by reciprocity and the number licensed in Maryland who were certified to be licensed in another state by reciprocity during the past ten years.

Fiscal Year	*Reciprocity*	*Certification*
1984-1985	148	54
1985-1986	191	70
1986-1987	206	75
1987-1988	197	57
1988-1989	228	86
1989-1990	187	103
1990-1991	212	98
1991-1992	178	86
1992-1993	192	119
1993-1994	190	88
1994-1995	183	52
1995-1996	229	105
1996-1997	184	142

Pharmacy Permits

As of April 30, 1997, one hundred five new permits to operate a pharmacy were issued.

Location	1996-1997
Counties:	
Allegheny	1
Anne Arundel	4
Baltimore	7
Calvert	1
Carroll	0
Cecil	1
Charles	0
Dorchester	0
Frederick	0
Garrett	4
Harford	5
Howard	0
Kent	5
Montgomery	13
Prince Georges	0
Queen Anne	0
St. Mary's	0
Somerset	0
Talbot	0
Washington	3
Wicomico	0
Worchester	0
County Totals	*44*
Baltimore City	*29*
State-Wide Totals	*73*

In addition to the issuance of new pharmacy permits for this annual year, the Board also issued fifty-three pharmacy permits for existing facilities that had a name, location, and/or ownership change(s).

Pharmacy Waiver Permits

In June, 1987, regulations were promulgated under COMAR, Title 10, Subtitle 34, Chapter 17, allowing waiver of full service requirements for recognized pharmaceutical specialties. As of April 30, 1997, the Board issued nine (9) new pharmacy waiver permits as follows: one (1) in Baltimore County, one (1) in Howard County, two (2) Allegany County, one (1) Frederick County, one (1) in Cecil County, and three (3) in Baltimore City. In addition to the issuance of new pharmacy waiver permits for this annual year, the Board also issued nine (9) pharmacy waivers for existing facilities that had a name, location, and/or ownership change(s).

Manufacturers Permits

New permits to manufacture drugs, medicines, toilet articles, dentifrices, or cosmetics were issued to two (2) entities during the year. In addition to the issuance of new manufacturer permits for this annual year, the Board also issued five (5) manufacturer permits for existing facilities that had a name, location, and/or ownership change(s).

Drug Distributors Permits
The Board issued fifty-two (52) new permits to distribute prescription drugs during the year. In addition to the issuance of new distributor permits for this annual year, the Board also issued eighteen (18) distributor permits for existing facilities that had a name, location, and/or ownership change(s).

Total Licenses and Permits
The total number of establishments licensed through the State of Maryland is 1,530 and the total number of licensed pharmacists is 6,222 as of April 30, 1997.

Legislation
The following bills either directly or indirectly affect pharmacy and were enacted by the 1997 General Assembly. These bills must be signed by the Governor to become effective.

SB 652 - State Board of Pharmacy - Scope of Practice

> The Bill updates many provisions applicable to modern pharmacy practice, including definitions of pharmacy practice activities such as compounding, dispensing and distribution of drugs. The Bill sets standards for permit holders and licensees, including drug storage requirements and requirements for equipment and personnel. The Bill also requires pharmacies dispensing to persons in Maryland via mail or common carrier to obtain a pharmacy permit. Pharmacists must now be available on the pharmacy premises, not necessarily in the pharmacy at all times and authorizes when and by whom inspections may occur. The bill also authorizes refills of certain drugs in some emergency situations.

SB 664 - State Board of Pharmacy - Disciplinary and Regulatory Authority

> The Bill authorizes the Board of Pharmacy to modify the requirements for conduct of licensees, requires examination of licensees by health care providers when needed to prevent public harm. The bill also authorizes the Board to disclose information to other health occupations regulatory bodies and to initiate programs to inform and protect the public. Peer review committees are authorized when needed to advise the Board in regulatory and disciplinary matters. In addition, the bill limits legal discovery of certain Board investigative records, and changes current provisions involving fines, and investigations.

SB 717 and HB 1229 - State Board of Pharmacy - Composition

> The Bill authorizes the Board of Pharmacy to improve Board composition by ensuring that representatives from most pharmacy practice areas are represented on the Board. This action will broaden the technical expertise represented on the Board. The number of Board members will be increased from eight to twelve, ten of whom are pharmacists and two consumers. Pharmacist member seats are allocated to specific practice settings with two at large seats. The Bill requires the Board to notify all licensed pharmacists of Board vacancies and the procedure for filling the vacancies

Cooperative activities
The Board maintained cooperative activities with the State Department of Health and Mental Hygiene; the University of Maryland School of Pharmacy; the Pharmacists Education and Assistance Committee; the Division of Drug Control; the Licensing and Certification Administration; other professional health licensing Boards & Commissions; the Maryland Pharmacists Association, the Maryland Society of Health

System Pharmacists; the Maryland Association of Chain Drug Stores; the Maryland Chapter of the American Society of Consultant Pharmacists; City, County and State Police; the National Association of Boards of Pharmacy; and all Pharmacy Boards and Schools of Pharmacy throughout the country.

Disciplinary Activities

The Board of Pharmacy receives complaints from the public concerning problems with the Board's licensees. Other complaints were received from the Division of Drug Control, Medical Assistance Compliance Administration, Licensing and Certification, State of Maryland Courts and other state boards of pharmacy. The wide range of complaints varied in severity. Listed below are statistics concerning the types of complaints for the period of May 1, 1996 - April 30, 1997.

Mislabeled prescriptions	6
Incorrect drug dispensed	29
Shortages of medication	2
Communication	3
Prescription not dispensed	1
Board action by another state	2
Inconsistent with professional standard	8
Continuing education	6
Impaired/chemical dependency	5
Total Complaints	62

During the period of FY 1996, seventeen (17) disciplinary orders were executed by the Board and became available as public information. These orders covered seventeen (16) pharmacists and one pharmacy; offenses included:

Pharmacists:	
Emergency suspension	2
suspensions with immediate Stay and probation	6
Full reinstatement	6
Surrender of license	2
Revocation	0

Pharmacy:	
Probation	1

During this period, the Board voted charges for violation of pharmacy law against 21 pharmacists and one pharmacy. Fifteen of these twenty-one cases have been concluded (included in the above statistics) and six are outstanding.

The Board has five additional outstanding cases from the previous year which have not been concluded. Of these, one pharmacist's license is currently suspended on an emergency basis pending final resolution. The Board has voted charges for formal action against the four remaining cases.

Some pharmacists were convicted of violating more than one provision of the Pharmacy Practice Act. Listed below are the types of violations according to the section of 12-313(b) of the Health Occupations Article and the number of pharmacists convicted of each:

(2) Fraudulently or deceptively uses a license; 1

(4) Provides professional services while 4

(i) Under the influence of alcohol; or

(ii) Using any narcotic or controlled dangerous substance, as defined in Article 27 of the Code, or other drug that is in excess of therapeutic amounts without valid medical indication;

(6) Willfully makes or files a false report of record as part of practicing pharmacy; 2

(14) Without first having received a written or oral prescription for the drug from an authorized prescriber, dispenses any drug for which a prescription is required; 4

(20) Is professionally, physically, or mentally incompetent;

(23) Is disciplined by a licensing or disciplinary authority of any other state or country or convicted or disciplined by a court of any state or country for an act that would be grounds for disciplinary action under the Board's disciplinary statutes; 2

(24) Violates any rule of regulation adopted by the Board; 3

Data Processing

The focus by the Board has very closely followed that of the Department and the Executive

Office. This focus has been on accountability and accessibility. Policies have been established similar to Federal laws making units responsible for the proper use of computer technology. The Department of Budget and Fiscal Planning promulgated DBFP Manual #95-1, relating to copyright infringement and ethics in June 1995 and required complete compliance by June 1996. The Board of Pharmacy met the requirements and the Department enlisted the assistance of the Board's Network Specialist to ensure compliance among 16 other professional health care licensing boards. The Board has assumed more control over manipulating the licensee data base by printing various forms of licensure information in-house on networked personal computers. Every Board staff has the ability to provide lists and prepare statistical reports based on licensee information.

The Department of Budget and Fiscal Planning has been implementing The Financial Management Information System (FMIS), the State's automated revenue and expenditure system. The Board anticipates having access to FMIS to verify Board financial transactions via a communication device. The Board also expects to participate in the Department's plans to broaden the INTERNET services, the Board's Pharmacist Compliance Officer utilizes this service for research in legal, compliance and disciplinary matters. The Electronic Mail (E-Mail) accounts are used to transfer information between the Board and the Office of the Attorney General, the Department, Board Members and outside service agencies.

Finances
Pharmacists renewing in fiscal years 1997 and 1998 have received a complimentary renewal license while the Board implements changes to the licensure renewal cycle. Pharmacists will renew their license every two years during their birth month. This has already reduced the Board's carryover from revenue in FY97 by a projected $266,000 and will reduce carryover in FY98 by another $266,000. The impact of this policy change is to significantly reduce the Board's carryover, thus yielding a revenue carryover amount sufficient to maintain the Board for the period of one year.

Financial Statement
The FY96 projected expenditures were $769,682 and the Board actually spent $742,174. It is also important to note that in FY96 the Board's actual revenues were $766,691. During FY96 only $24,000 was contributed to carryover.

FY96 Actual	
Budget	$ 742,174
Revenue	$ 766,691
Indirect Costs	$ 149,925
Carryover Funds	$ 24,517

FY97 Projected	
Budget	$745,079
Revenue	$456,825
Indirect Costs	$126,381
Carryover Funds	$(288,254)

Regulations
During 1997, as required by Law, the Board reviewed all of its regulations. The Board has the following amended, new, or repealed regulations in progress:

10.34.02 -	Examination for Licensure and Internship Professional Experience Programs (amended)
10.34.09 -	Fees (amended)
10.34.20 -	Prescription Orders Transmitted by Facsimile Devices (amended)
10.34.02 -	Oral Competency

Continuing Education
Continuing education (C.E.) program approval is requested monthly by program sponsors and program attendees for programs not automatically approved by Maryland regulations for Continuing Education. Requests are approved monthly or returned to the sponsor or attendees for additional information

The 1996 license renewal process resulted in 33 extensions to obtain the required Continuing Education credits.

Continuing Education requirements are regularly included in disciplinary cases and reviewed for compliance prior to resolution of the disciplinary action.

The 1996 Continuing Education Audit is in progress. Eighty-six percent of those pharmacists audited have sent copies of their documentation of credits to the Board's office. Of this 86%, 88% of the audits have been approved as being in compliance.

A new Board member has assumed the position of Continuing Education Coordinator. This member, Wayne Dyke, P.D., will be assisted by consumer Board member Barbara Faltz-Jackson.

The scanning equipment is anticipated to be used to scan Continuing Education documents so that a 100% audit of pharmacists renewing their licenses can be implemented.

The change in the Continuing Education requirement for licensure was instituted with the 1996 license renewals and will continue with the 1997 license renewals. With these two sets of renewals, pharmacist will have future renewals in their birth month. The Continuing Education audit process will remain the same. All pharmacists renewing from January through December of a calendar year will be audited in January or February of the following year.

The Board became a provider of Continuing Education in 1996, with the presentation on the Revision of the Pharmacy Practice Act providing a 1 Continuing Education credit program. This program was presented by various Board members to numerous pharmacist and other health care provider organizations.

Secretary/Treasurer's Message

The Board has new staff members, which have been with the Board for part or all of the past year. Monique Cheatham, Office Secretary III, Carol Gibbs, Office Secretary II, and David Denoyer, J.D., R.Ph., Pharmacist Compliance Officer are the new staff members.

There are three new Board members, also, Wayne Dyke, P.D., Stanton Ades, P.D., and Reverend William Johnson, a Consumer Board member.

As of May 1, 1997, President David Russo, P.D., M.B.A., succeeds President George Voxakis, Pharm D, and Secretary/Treasurer Irving Lottier, P.D., succeeds Secretary/Treasurer Dorothy Levi, R.Ph. The Governor will be appointing two new Board members to assume the positions of George Voxakis, who will be completing 10 years of service, and Dorothy Levi, completing 9 years of service.

During this past year, the Board has dealt with the usual responsibilities: Board examinations in June and September, pharmacist license renewals in July, establishment permit renewals in December, the General Assembly session from January to April, Continuing Education extensions in October and CE audit in March.

Regulations awaiting approval include Electronic Transmission of Prescriptions, Examination Fees, and Oral Competency Requirements.

A scanning system was purchased during this past year. It is in place in the Board's office and has had its software programmed as of March, 1997. The Scanner will be used for pharmacist renewals, establishment renewals and other documents of the Board. A Board staff member has attended a software programming class in order to do in-house programs.

A special Board Project, which began in September 1995, with the formation of a Task Force to recommend revisions of the Pharmacy Practice Act to the Board made its report at the May, 1996, Board meeting. Following that report, the Board reviewed the revisions, revised some revisions, prepared a Presentation Notebook, made presentations to numerous pharmacist and allied health professional organizations, obtained legislator sponsors for three pieces of legislation reflecting all revisions, presented testimony at House and Senate Committee hearings and waited for the outcome of the legislation. At the suggestion of the Senate sponsor of the legislation, two sections of revisions were temporarily withdrawn so that further discussions could be held to reach agreements with all parties involved. After making these withdrawals and accepting suggested amendments to the remaining legislation, the Board was rewarded with all three pieces of legislation passing.

Following this year's Legislative Session, the Board has made plans to reformulate the Task Force, form workgroups to prepare legislation on the withdrawn revisions to the Practice Act, reconvene a Task Force Subcommittee to review and revise current regulations, and reactivate the Board's Pharmacy Practice Committee to develop new sets of regulations. A substantial amount of work is still needed to take new proposed legislation to the Legislature in the 1998 Session.

Projects continuing throughout this past year include developing a media campaign for health education and a public service program; starting the new pharmacist license renewal system according to pharmacists' birth month; instituting a written reciprocity law examination, which will begin with July's candidates; and implementing oral competencies tests for all licensure candidates.

With the National Association of Boards of Pharmacy (NABP) starting computer NAPLEX exams as of June, 1997, the Board will be changing its exam schedule from June and September to June and October. NABP will be ready to start a computer Law exam in 1998. Then the Maryland Board will only be administering a Lab Exam.

The Board is continuing to provide financial assistance to the Pharmacist Education and Assistance Committee, formerly the Pharmacist Rehabilitation Committee.

During the past year, the Board has revised a number of its applications: pharmacy, distributor, and manufacturer permit applications and Continuing Education Approval Forms.

The Board has dealt with a controversial topic during the past year: patient confidentiality of prescription records. Questions of compliance are numerous. The Board's interpretation of Maryland's Law has been on a case-by-case basis, and research is continuing to aid the Board in giving more informed opinions.

The Board has been extremely busy this year with many major accomplishments. The year ahead appears that it will be as active.

The Board encourages your participation, your questions, and your comments and suggestions.

Respectfully Submitted,

Dorothy L. Levi

Dorothy Levi, R.Ph.
Secretary/Treasurer

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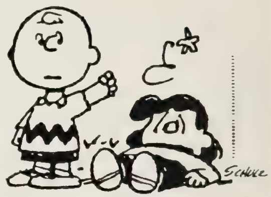

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Mandatory Early Discharge - After Uncomplicated Childbirth

Tripuri Strackbein, Student
UMAB School of Pharmacy

During the last three to four years, the healthcare industry in the US has widely adopted a practice of discharging mothers and their children within twenty-four hours of normal vaginal delivery. Does this practice, which is driven by the desire to significantly lower healthcare costs, take into consideration the elements of risk associated with early discharge, and does it succeed in maintaining an acceptably low rate of infant morbidity?

ABSTRACT

Our objective is to assess the advisability of discharge within twenty-four hours of birth, in terms of the effect on the health of the newborn. We cite the findings of several studies related to the ability to detect certain maladies common to newborns, including phenylketonuria (PKU), congenital hypothyroidism, congenital adrenal hyperplasia, and bilirubin toxicity within the framework of a twenty-four hour discharge policy. In addition, we establish the connection between postpartum follow-up treatment and early discharge, evaluate the early discharge policy in terms of the effect on infant morbidity, and discuss the problems associated with evaluating the total costs of early discharge programs. Based on the number and severity of ailments to which the newborn is susceptible in the first few days of life, we conclude that careful monitoring of the infant is necessary during this period. The final decision to discharge early rests with the family and attending obstetrician, following the guidelines established by the Committee on Fetus and Newborn. In light of the failure to always provide outpatient follow-up, insurers should not be permitted to require discharge earlier that seventy-two hours.

Over the past few years, the healthcare industry in the US has adopted a policy of discharging mothers and their newborns within twenty-four to forty-eight hours of normal vaginal delivery. Unique among the developed nations, this policy is now applied to approximately 40% of neonates and their mothers[1]. Proponents of this policy, primarily health maintenance organization (HMO) representatives and other third-party payers, proclaim that it is cost effective, saving the US nearly four billion dollars annually in health care costs (at a rate of $1,000 per day and approximately four million births per year[2]), while maintaining a high standard of care. Opponents of the policy claim that it can be unsafe for the infant and the mother[3]. Thus, the primary issues are the impact of the policy on the wellness of the mother and newborn and on health care costs.

A number of studies have been performed in an effort to gather empirical data on the effects of this new policy. We will present the findings of these studies, as well as statistical and anecdotal information which are pertinent to the issue of early discharge. Since it is beyond the scope of this paper to discuss in sufficient detail every possible health implication of the policy, we will limit our discussion to the policy's effects on one of its most serious potential consequences, namely that of infant morbidity. The Maternal and Child Health Bureau of the Health Resources and Services Administration has identified a number of neonatal health issues as pertinent to early discharge and infant morbidity. These include reduced infant care in the days following birth, including incomplete screening of infants for diseases such as phenylketonuria (PKU), congenital hypothyroidism, congenital adrenal hyperplasia, and bilirubin toxicity, and lack of follow-up treatment after discharge[4]. Finally, we will present our overall evaluation of the evidence and offer our conclusions regarding the advisability of the policy.

Of the four million infants born per year in the US, between 160 and 400 suffer from PKU[5]. PKU patients lack an enzyme that breaks down an amino acid, phenylalanine, contained in food. As a result, the phenylalanine levels rise in the blood and if left untreated can cause mental retardation. Since 1961, all the states including the District of Columbia, Puerto Rico, and the US Virgin Islands have adopted screening tests to detect high levels of phenylalanine and prevent the progression of PKU[6]. Traditionally, this test was performed on three-day-old infants prior to discharge using a 4 mg/dL cutoff in forty states, 3 mg/dL cutoff in six states, and greater than 2 mg/dL cutoff in the remaining seven states[7]. In affected infants, the level of phenylalanine in the blood rises during the first few days of life, but, according to a number of studies, blood samples taken from many of these newborns in the first twenty four hours of life will not exceed the cutoff levels referred to above[8]. Therefore, without follow-up screenings, the probability of PKU going undetected is increased by early discharge. Even at a relatively low cutoff level of 2 mg/dL, Doherty et al recommend follow up screening to ensure detection of substantially all of the cases of PKU[8].

Screening for congenital hypothyroidism is performed in all fifty states and the District of Columbia, Puerto Rico and the US Virgin Islands.[9] According to the Committee of Genetics, this disorder results from an insufficient production of thyroid hormone and affects between 800 and 1000 newborns annually in the US. If not detected or not promptly treated, the patient suffers from mental retardation, growth abnormalities, neurological deficit, and/or deafness. The Committee reports that false positives may result from taking specimens during the first 24 to 48 hours of life[10]. A separate study conducted by Saslow et al found that, of the 515 initial screenings performed within 24 hours of birth for infants of normal weight born over a thirty-one day period, 91% would have been false positives[11]. The treatment of congenital hyperthyroidism involves oral levothyroxine therapy, which is initiated immediately following diagnosis. Thus, a false positive screening due to early discharge would result in a wrong diagnosis and unneeded treatment. High levels of thyroxine cause behavioral problems[10].

The most common form of congenital adrenal hyperplasia, 21-hydroxylase deficiency, results in excessive androgen production, which can be detected through neonatal screening for 17-hydroxyprogesterone (17-OHP).[12] The incidence rate in the US is one in 12 000 births, or approximately 330 cases per year.[13] Affected neonates suffer from salt wasting, which can cause shock, simple virilizing, or "masculinization" of female genitalia, and short stature due to premature fusing of bone.[12] Since blood levels of 17-OHP are often elevated during the first twenty four hours of life, screening performed during this period is likely to result in false positives, although further study is needed. Treatment usually involves administration of glucocorticosteroids.[12] Again, false positives could lead to incorrect diagnosis and unneeded treatment, with concomitant adverse physiological effects and unnecessary postnatal healthcare costs.

Jaundice, a symptom of hyperbilirubinemia, accounts for about 85% of the 1 to 4% of newborns who are readmitted to hospitals during their first week of life[14]. There is anecdotal evidence of twenty-two infants being readmitted following early discharge who have developed hyperbilirubinemia-induced brain damage, or kernicterus, in the past four years.[14] Cases of kernicterus were virtually non-existent in the US in the twenty years prior to the adoptions of the 24-hour discharge policy.[15] Since high blood levels of bilirubin are not easily detectable within twenty-four hours[16], hyperbilirubinemia can go undetected due to discharge within this time period.

The findings of each of the studies presented here highlight the need for follow-up care in the event that a mother and child are discharged early. Unfortunately, the majority of states do not require mandatory follow-up. There is also a compliance issue. Follow-up screening requires that the mother and infant return to the institution that they were discharged from. However, even in programs where mothers signed agreements requiring them to return to the hospital for no-charge follow-up treatment, between 10% and 25% of them failed to avail themselves of this service.[17,18] In light of the fact that mothers are often cognitively dysfunctional after labor, including memory deficits,[19] it is perhaps unsurprising that mothers in this exhausted state are unable to provide proper care for themselves, let alone their infants, as an early discharge forces them to do. A twenty-four hour period is insufficient to alert the mother to all of the problems she may encounter in the first few days of motherhood, especially in cases where the mother has received little prenatal training. Indeed, the number of babies suffering from dehydration and malnutrition is on the rise.[20] This is a direct result of improper feeding of the infant. An additional day or two in the hospital would permit the mother to recuperate and absorb the information she needs to care for her infant.

In a managed care environment, where there is an emphasis on following established policies, it is too easy for a health care institution and its practitioners to over-rely on these policies in making decisions regarding a mother's and infant's suitability for early discharge and follow-up treatment. Indeed, one study found that the first follow-up visits were routinely scheduled as many as two weeks after discharge without regard to the presence or absence of risk factors at the time of discharge.[21] In an effort to minimize costs, mothers and infants may be released before necessary steps have been taken to perform proper screenings and provide them with the treatment and training they need to ensure their healthful recuperation in the days following discharge. Moreover, the studies done thus far tend to address narrow population groups. Larger studies, representative of the overall population, are needed.

Unfortunately, there has been a marked lack of research into the impact early discharge policies have on the nation's *total* healthcare bill. The cost studies performed to date support the obvious conclusion that a shorter stay in the hospital is less expensive than a longer one.[22] This does not account for the costs associated with readmissions for treatment of avoidable ailments, such as jaundice. In fact, in these cases' costs are frequently higher than they would have otherwise been, since there are administrative costs associated with readmitting a patient (sometimes to a different hospital than the one in which the birth occurred). Nor does it address the costs of emergency room treatment and increased home health and doctors office visits,[21] nor of the costs to treat life-long debilitation which could have been prevented by an additional day or two in the hospital at birth. In addition, the cost of increased liability insurance coverage must be accounted for. Thus, there is a desperate need for comprehensive research in this area. What is clear, of course, is the fact that early discharge policies initially shift costs associated with birth from third-party payers to the family. While many families have access to prenatal counseling and quality postnatal care, there are nonetheless many women who do not. Therefore, the incidence of infant morbidity and emergency care is likely to be higher among these families than they would be in the absence of early discharge policies.

It has been pointed out that the risk of nosocomial infections is increased with length of stay.[23] Indeed, this risk must be weighed against the need to keep newborns in the hospital for a period of time sufficient to ensure proper screenings. Most of the serious maladies which threaten the newborn infant can be screened for over a three day time period. Thus, once the proper screenings have been performed, there is no compelling reason for healthy infants and their mothers to remain in the hospital. We feel it is safe to say that stays beyond 3 days should be discouraged.

In the end, while the ultimate responsibility for the decision to discharge early rests with the obstetrician and the family, we feel strongly that the infant's and mother's health and the likelihood of follow-up must be taken into account when making this decision. The American Academy of Pediatrics' Committee on Fetus and Newborn prepared in 1980 a list of guidelines for pediatricians to follow in identifying candidates for early discharge.[24] These guidelines include the provision of follow-up care for at least three days after early discharge and demonstrated ability to provide post-discharge care on the part of the mother. In refusing to pay for more than a twenty-four hour postpartum stay in the hospital, third-party payers assume that these guidelines will be met. The studies cited have shown, however, that this is not always the case. The family should not be pressured to leave the hospital before they feel ready by a lack of insurance coverage beyond the twenty-four hour period. Thus, we feel that if need be, regulation should be passed requiring insurers to pay for hospital stays of up to three days for normal deliveries, if deemed necessary by the family and attending obstetrician.

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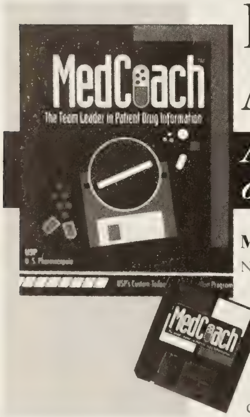

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The Maryland Poison Center 1996 Annual Report

The Maryland Poison Center (MPC) is a division of the University of Maryland at Baltimore School of Pharmacy and is certified by the American Association of Poison Control Centers as a regional poison center for Maryland. The following is a report of the activities of the MPC during 1996.

1996 was another busy and exciting year for the Maryland Poison Center. In addition to managing more than 36,000 poisoning or overdose cases, in September we switched from a paper-based system to an on-line data entry system. We're using this system to better track, manage and report poisoning cases. The data in this report reflects the efforts of the Maryland Poison Center to provide the most up-to-date poison treatment and prevention information possible. ***The goal: to save lives and save health care dollars!***

Call Volume

During 1996, the MPC managed 55,745 calls. While 36,821 involved humans, 18,924 calls were requesting information where no human exposure occurred.

Age

The majority of poison exposures (55.6%) involve children under the age of six years.

Age (Years)	Number	%
<1	2,326	6.3
1	6,617	18.0
2	6,467	17.6
3	2,921	7.9
4	1,329	3.6
5	798	2.2
6-12	2,427	6.6
13-19	2,818	7.7
20-29	2,953	8.0
30-39	3,282	8.9
40-49	2,042	5.6
50-59	970	2.6
60-69	527	1.4
> 70	702	1.9
Unknown	627	1.7
Total	**36,821**	**100.00**

Gender

In 1996, 49.2% of exposures involved males, 50.6% were in females, and 0.2% unknown sex of the victim.

Caller

Of the calls to the Maryland Poison Center in 1996, 80% came from the general public, 15.4% from physicians and nurses, and 4.1% from emergency medical responders, pharmacists, or other health professionals.

Geographic Distribution

Area	Number	%
Allegany	424	.99
Anne Arundel	5,247	12.28
Baltimore County	7,584	17.75
Baltimore City	7,706	18.03
Calvert	634	1.48
Caroline	233	0.55
Carroll	1,574	3.68
Cecil	780	1.83
Charles	682	1.60
Dorchester	203	0.48
Frederick	1,173	2.75
Garrett	196	0.46
Harford	2,156	5.05
Howard	1,925	4.50
Kent	158	0.37
Montgomery	2,609	6.11
Prince Georges	2,352	5.50
Queen Anne	265	0.62
Saint Marys	739	1.73
Somerset	142	0.33
Talbot	298	0.70
Washington	933	2.18
Wicomico	488	1.14
Worcester	388	0.91
Unknown County/ Unknown State	3,843	8.99
Total	**43,732**	**100.00**

Circumstance

Acute exposures accounted for 90.07% of the total calls, acute-on-chronic were 6.93% of calls, and 1.96% were chronic exposures and 1.42% were unknown exposure acuity.

Unintentional poison exposures were tracked by the Maryland Poison Center and categorized by the type of exposure. These exposures fall into seven categories: general (22,453 exposures, 60.98%); occupational (678 exposures, 1.84%); environmental (649 exposures, 1.76 %); therapeutic error (2,792 exposures, 7.58%); misuse (2,386 exposures, 6.48%); bite/sting (740 exposures, 2.01%); food poisoning (119 exposures, 0.32%; and unknown circumstances (17 exposures, 0.05%). In total, there were 29,834 unintentional poisoning exposures reported to the Center in 1996.

There were 6,041 ***intentional*** poisonings handled by the Center. These included poisonings by suicide attempts (4,535 exposures, 12.32% of total); misuse (749 exposures, 2.03%); abuse (456 exposures, 1.24%); unknown (301 exposures, 0.82%). Intentional poisonings accounted for 16.41 of the cases handled by the Center in 1996.

In addition to general and intentional poison calls, the Maryland Poison Center also intervened in situations where poisonings occurred for ***other*** reasons. 63 exposures (0.17% of total) were due to contamination and/or tampering. 149 poisonings (0.41%) were determined to be of malicious intent. Adverse reactions to drugs, foods, and other products accounted for an additional 644 calls to the Maryland Poison Center. There were 90 unknown exposures (0.24%).

Site of Exposure

Not surprisingly, the vast majority of poisonings occur at home. According to the statistics gathered, poisonings occurred at the: residence (34,041, 92.45%); workplace (909, 2.47%); school (692, 1.88%); public area (320, 0.87%); health care facility, (69, 0.19%); restaurant (27, 0.07%); other, (481, 1.31%); unknown (282, 0.76%).

Treatment Location

71.90 percent or 26,476 cases of poisonings were treated in non-healthcare facilities. The Maryland Poison Center referred patients to health care facilities for treatment in 24.24% of 36,821 cases. The outcomes of those referrals are:

Treated & Released	5,308	14.42
Admit to Critical Care	1,059	2.88
Admit to Non-critical Care	797	2.16
Admit to Psychiatry	1,269	3.45
Lost to follow up/ Left AMA	492	1.34
Other	633	1.72
Refused referral	591	1.61
Unknown	196	0.53

Route of Exposure

The vast majority of poisonings occurred from taking agents orally (30,359 cases, 76.73%); ocular (2,632, 6.65%); dermal (3,655, 9.24%); inhalation (1,901, 4.80%); bite/sting (750, 1.90%); parenteral (132, 0.33%); aspiration (59, 0.15%); other (46, 0.12%); unknown (33, 0.08%). Total 39,567 cases.

Note: The total cases by route of exposure is greater than the number of cases reported. This is because some patients had more than one route of exposure.

Medical Outcome

The medical outcome is assessed based on the inherent toxicity of the agent and the severity of the clinical manifestations. In 17,988 cases (48.85% of total), the agent was non-toxic or had no adverse health effects on the patient. Minor/minimal effects were reported in 15,567 cases (42.28%), moderate effect in 1,706 cases (4.63%), major effect in 148 cases (0.40%), death in 21 cases (0.06%), unrelated effect in 853 cases (2.32%), and unknown/potentially toxicin 538 cases (1.46%).

Deaths

Age (Years)	Sex	Substance
24	F	Amitriptylline/ Carbamazepine
35	F	Unknown Drugs
42	M	Heroin/Homicide
43	F	Phenytoin
43	F	Phenytoin
45	F	Acetaminophen/ Oxycodone
45	F	Amitriptylline
47	F	Amitriptylline/ Alprazolam
50	F	Verapamil/ Sumatriptan
51	M	Methanol
54	M	Ethylene Glycol
55	F	Procainamide/ Sotalol
56	M	Aspirin/Ethanol
61	F	Minoxidil
62	F	Phenylzine/ Phenformin
70	F	Lithium
75	M	Acetaminophen
78	M	Procainamide
Unknown	F	Aspirin
Unknown	M	Methanol
Unknown	M	Acetaminophen/ Ethanol

Agents Involved

This report summarizes the number of agents involved in the human exposure cases. Because of switching to a new data collection system, not all cases had the substance coded.

Agents	Number	%
Drugs		
Analgesics	1,395	12.69
Anesthetics	36	0.33
Anticholinergics	55	0.50
Anticonvulsants	168	1.53
Antidepressants	389	3.54
Antihistamines	987	8.98
Antimicrobials	326	2.97
Asthma therapies	140	1.27
Cardiovascular drugs	347	3.16
Cough & Cold preparations	1,030	9.37
Electrolytes/vitamins, minerals	233	2.12
Gastrointestinals	300	2.73
Hormone products	122	1.11
Muscle relaxants	45	0.41
Sedative hypnotics	138	1.26
Stimulants	124	1.13
Topicals	361	3.28
Veterinary products	50	0.45
Total: Drug Products	***6,246***	***56.83***
Non-Drugs		
Adhesives, glues	34	0.31
Alcohols	440	4.00
Arts, Crafts, Office Supplies	317	2.88
Automotive products	185	1.68
Batteries	33	0.30
Bites & envenomations	241	2.19
Building/Construction Products	215	1.96
Chemicals	135	1.23
Cleaning: Household	687	6.25
Cleaning: Industrial	71	0.65
Cosmetics/personal care	782	7.12
Food/ Food poisoning	80	0.73
Foreign Bodies	191	1.74
Fumes, gases, vapors	199	1.81
Hydrocarbons	221	2.01
Insecticides	111	1.01
Lacrimators	51	0.47
Mothballs	52	0.47
Mushrooms	32	0.29
Plants	503	4.58
Rodenticides	79	0.72
Swimming pool/Aquarium Products	30	0.27
Tobacco products	55	0.50
Total Non-Drugs	***4,744***	***43.17***
Total Agents	**10,990**	**100.00**

Educational Programs

The Maryland Poison Center offers a wide variety of professional education and public information each year. The center held 19 professional education programs (including hospital in services and grand rounds) and 17 public education programs. The MPC also sent materials for 29 other health/safety fairs. Also sponsored were two continuing education seminars: "Update: Poisoning Emergencies" for health professionals and "Poison Prevention Education Workshop" for those interested in teaching about poison prevention.

In addition to the programs listed above, the Maryland Poison Center serves as an important site for experiential training for a variety of health professionals in Maryland. In 1996, the MPC hosted:

15 doctors of pharmacy students
12 nursing students
11 emergency medicine residents
2 family practice residents
2 pediatric residents
1 pediatric emergency medicine fellow
30 paramedic students

1996 Maryland Poison Center Staff

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Continuing Education for Pharmacists

Volume XIV, No. 12

Patient Counseling: Homeopathy, Part 1: Introduction

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Goals. The goals of this two-part series are to review the concepts of homeopathic medicine and comment on how they differ from allopathic (conventional) medical practices; explain the origins of homeopathy and comment on reasons for its resurgence; and discuss the preparation of homeopathic dosage forms.

Objectives. At the conclusion of this series, participants should be able to:

1. differentiate between the concepts of homeopathic and allopathic medicine;
2. recognize the definition of terms used in homeopathy;
3. exhibit an understanding of the principles of homeopathic medicine; and
4. demonstrate knowledge on homeopathic dosage forms and their preparation.

A professional development program made possible by an educational grant from

SEARLE

Few topics capture the attention of pharmacists and the public to the extent of homeopathic medicine. This form of *natural* medicine, along with herbal remedies, has made a resurgence since its demise in the early and mid-1900s. Several studies have been conducted to assess the public's attitude toward conventional physician-directed health care. One showed that more than 90 percent of Americans try an OTC product or a home remedy before contacting a physician about their complaints. Another study reported that one third of Americans had sought some type of alternative care rather than making an appointment with a physician for diagnosis and treatment.

The information available on natural medicine has exploded over the last few years, not only in the nutrition-oriented press, but also in magazines popular with the lay public, computer information networks, and even professional pharmacy journals.

Today, individuals are seeking safe and effective ways to alleviate symptomatic complaints with minimal side effects. They are becoming more interested in not being sick in the first place, rather than the traditional "treat the illness after it occurs" philosophy of medicine in this country. Americans are concerned about pollution and the environment, and the holistic (mind/body/spirit) approach to good health. They are more aware of the adverse effects of drugs, and the morbid and deadly events sometimes associated with hospitals.

A major differentiating philosophy between homeopathy and traditional (allopathic) medicine is contained in their names. The term *homeopathy*, first expressed by German physician Samuel Hahnemann in 1807, was derived from the Greek words *homiosis*, meaning "similar" or "like," and *pathios*, meaning "suffering." The name was meant to demonstrate its guiding principle, "like cures like," which Hahnemann describes as the *Law of Similars*. This concept is based on the belief that, if a substance causes an adverse effect, diluting that substance to an infinitesimal concentration can reduce or cure the symptoms of the patient.

Hahnemann, who is considered to be the Father of Homeopathic Medicine, is also credited with coining the term *allopathy* from the Greek stem *allo* meaning "other" for its prefix. In his day, the "other" traditional medicine consisted of bleeding and the application of leeches, enemas and emetics "purging," and the administration of poisons such as lead and mercury. Therefore, Hahnemann's approach fostered a more humane, less harmful, and more disease-oriented treatment than the then traditional methods, which often debilitated the patient to such an extent that it was difficult to survive the treatment.

The Law of Similars, as expressed by Hahnemann, states that by looking at the symptoms of a disease and matching them to the toxic effect of natural substances, one can improve or cure the disease by administering extremely dilute doses of the natural substance. A leading example of this concept is ipecac. A therapeutic dose of syrup of ipecac, as is used in treating poisoning in the 15 to 30ml range, will induce vomiting in healthy subjects. However, a tremendously dilute "homeopathic" dose of ipecac can, proponents claim, relieve nausea and vomiting caused by disease, drugs, or foods.

The Law of Similars can be summarized as:

- every substance that causes a pharmacologic effect on healthy humans produces characteristic symptoms;
- every disease causes characteristic symptoms; and,
- every disease can be treated by administering a small homeopathic dose of a substance that causes those same symptoms.

Since the inception of this concept, the symptoms caused by over 2,000 substances have been catalogued along with the illness for which they can be used. Homeopathic medicine, therefore, became the first attempt at a rational scientific basis of therapy involving an examination of a patient's symptoms and how they relate to disease, a knowledge of the action of the medication used in treatment, and a determination of the correct dose to use. The principles that describe homeopathy seem obvious when applied to today's medicine. Dr. Hahnemann had made a major leap forward toward what we currently know as homeopathy.

Today there still remains a major difference between homeopathic and traditional medicine, but it comes from the other end of the continuum. Homeopathic supporters claim that homeopathic medicines stimulate the body's own forces to cure illness without inducing the side effects of drug therapy. Modern traditional medicine, on the other hand, is based on the administration of antibiotics and other antimicrobials to kill invading organisms; replacement of insufficient or inhibition of excessive hormones, enzymes, and neurotransmitters; and interference with the body's normal processes (i.e., calcium channel blockers, ACE inhibitors) in order to alleviate disease symptoms.

Another extremely important component of homeopathic medicine claimed by proponents is the involvement of the *entire patient* by including proper diet, exercise, and sleep as important components of the treatment plan. Patients are urged to eat well and avoid excessive behaviors that agitate or depress them. They should also increase activities that make them happy. Part of the training of homeopathic practitioners involves assisting them in developing a caring, empathetic, and tolerant attitude toward their patients.

Table 1 lists a glossary of terms that will be mentioned throughout this lesson series.

As stated earlier, the originator of the concept of homeopathic medicine was Samuel Hahnemann, a physician living in Leipzig, Germany, at the turn of the nineteenth century. Economically, things were not as lucrative for physicians then, compared to today. In order to support his wife and seven children, Dr. Hahnemann, who was fluent in several languages, made a living by translating foreign texts into German.

Table 1
Glossary of Terms

ALLERODES	Dilutions of antigens which induce antibody formation.
ATTENUATION	Diluting homeopathic substances to the point they are curative rather than toxic.
BIOENERGY	The intrinsic healing power of the body. An essential concept in holistic medicine.
HOLISTIC THERAPY	Therapy that takes into account the patient's whole person (body, mind and spirit), and attempts to restore the balance or equilibrium of bioenergetic forces to restore health.
HOMEOPATHY	The concept of treating the characteristic symptoms of a disease with diluted concentrations of a substance that causes those characteristic symptoms. Derived from the Greek words *homiosis* (similar) and *pathios* (suffering).
ISODES	Dilutions of botanical, chemical or zoological substances.
POTENTIZATION	Diluting a homeopathic substance to cause it to gain in its remedial properties.
PROVINGS	Dosing a human with a homeopathic substance until the entire range of its characteristic symptoms are determined.
SUCCUSSION	Shaking a diluted solution of a homeopathic substance vigorously to increase its energy and remedial properties.
TAUTOPATHY	Using dilutions of a homeopathic substance to counteract the toxicity of the same substance.
TRITURATION	Vigorously mixing insoluble forms of a homeopathic substance, either by hand or machine, to increase its energy and remedial properties.

One of the books, *A Trecis on Materia Medica* by respected

Scottish physician and teacher Dr. William Cullen, interested him greatly, most specifically, Cullen's review of Peruvian bark. In those days it was believed that the active component of the Quina Quina tree was cinchona. Today we know it as quinine, the alkaloid contained therein. Then, as now, it was used to treat malaria.

Notes written during his translation of the book showed that Hahnemann became extremely interested in cinchona to the point that he began experimenting on himself by taking it twice a day. He noted that, after taking a dose, he became cold, then drowsy, then languid. This advanced to palpitations of his heart, quickening pulse, intolerable anxiety and trembling, pulsating headaches, pulsing in his face, thirst, and intermittent fever. These symptoms occurred whenever he took another dose, and lasted two to three hours. Each time he discontinued the cinchona, he returned to good health.

Noticing that his symptoms were the same as those of the disease for which the cinchona was used (malaria), he began to experiment with other drugs of his day. By the time of his death, Hahnemann had tested, or as he called it "proved," over 250 different drugs. His research led him to dilute the drugs more and more until he had arrived at what he considered to be the ideal solution (potentization). Since then many other substances have been catalogued by proponents as being useful in treating disease.

When Hahnemann died in 1841, he had not witnessed the tremendous rise in popularity of homeopathic medicine. It has been reported that, by the late 1890s, the concept had spread throughout the world with an estimated 400 million patients receiving homeopathic remedies. In the United States by 1900, there were 22 colleges of homeopathic medicine, over 100 homeopathic hospitals, and approximately 15,000 homeopathic pharmacists.

Interest in homeopathy began to decline. Antagonism toward it by the allopathic physicians persisted and grew. The story is told that the American Medical Association was formed in order to break the monopoly of homeopathy in the United States.

A number of factors contributed to the decline of homeopathy. Among them were the discovery of nitrous oxide and ether for general anesthesia during surgery, discovery of the existence of bacteria and antiseptics to treat wounds, and discovery of salvarsan, which was the first chemical "wonder drug" proven to be effective in treating syphilis. The latter drug led to chemical companies spending huge amounts of money on research and development of therapeutically active chemicals that could be patented, hopefully resulting in significant return on investment.

In 1935, sulfanilamide was proven to exert antibacterial activity. In relatively short order sulfathiazole, amphetamines, barbiturates, and penicillin were discovered. The country and world were mesmerized by these "instant cures," and lured by the marketing forces of the international drug companies. Physicians were persuaded to shift from the natural and compassionate, yet unspectacular approach to healing seen with homeopathy, to the more dynamic, modern wonder drugs of the era.

By the time World War II began, allopathic medicine had the support of multinational drug companies which spent millions of dollars in research. Again, this became worthwhile because there was an economically beneficial outcome -- a patent for the drug. With homeopathic medicine, there was no such financial incentive.

Nearly all homeopathic medicines had been "proved" on a small scale by individuals dedicated to their belief and to the advancement of the knowledge thereof. Rather than a few large chemical drug firms, homeopathy relied on large numbers of small homeopathic dispensaries.

More recently there has been a resurgence of homeopathic practice. The number of pharmacies stocking at least a few homeopathic remedies is now in the tens of thousands. In *FDA Consumer*, it is stated that the homeopathic drug industry was developing at what the agency called an alarming rate. Due to a concern in 1988, FDA issued a compliance policy entitled, "Conditions Under Which Homeopathic Products May Be Marketed."

Herein lies one of the major misunderstandings of homeopathic medicines. Opponents claim they are unregulated, unproved, and potentially dangerous. Proponents claim that the homeopathic drug industry is governed by the same regulations and regulatory groups as the rest of the drug industry. They point out that they must comply with the provisions of the FDA, including the CGMP (Comprehensive Good Manufacturing Practices), Tamper Evident Packaging, Drug Listing Act, and the FDA Compliance Policy Guidelines. Homeopathic firms must register with FDA, and their products must comply with FDA requirements. While homeopathic drugs are not required to have an NDC number at this time, their products must be listed with the FDA.

Historically, homeopathic medicines were exempted from USP standards. This relates back to 1938 when FDA was granted far more extensive powers to regulate the food, drug, and cosmetic industries. Congress recognized two different reference standards for drugs: the *United States Pharmacopoeia* for allopathic drugs and the *U.S. Homeopathic Pharmacopoeia* for homeopathic medicines. In response to meeting with FDA, the USHP convention issued the first volume of its *Homeopathic Pharmacopoeia Revision Service* (HPRS) in 1988.

Table 2
Opinions Presented to Explain the Resurgence of Homeopathic Medicine

- The public is more health conscience and wants to be more involved in staying well rather than waiting for disease to appear and then treating its symptoms.
- The "green movement" toward natural, organic foods with no preservatives or other additives; rejection of synthetic and processed foods.
- The public is more aware of environmental pollution and some actually consider drugs to be part of the pollution.
- The increased cost of prescription drugs when compared to homeopathic remedies.
- The growing animal rights movement that criticizes the use of animals in drug testing of allopathic medicines.
- Homeopathic remedies are becoming available to a greater extent.
- Patient discontent with the way health care is developing with the loss of choice for the physician they see, the hospital they can go to and the pharmacist they can deal with.
- The precept that current health care is mechanistic, preoccupied with authority, disregarding of the total patient and his/her feeling or emotions. Physicians are more willing to treat patients based on the results of laboratory tests and information from instruments rather than relying on understanding patients or their needs.
- The potential for serious side effects caused by drugs, some of which have led to morbidity, death and their removal from the market.
- The promise of instant cure for all diseases has not been fulfilled.
- The potential for addiction to psychoactive drugs.

Since 1938, and more recently through the revision service, substances with monographs in the HPRS are recognized as official drugs in the Food, Drug, and Cosmetic Act and Code of Regulations. The HPRS updates manufacturing methods, provides guidelines for whether the homeopathic drug requires a prescription or can be purchased OTC, and publishes current monographs on all official homeopathic drug products.

The major difference between homeopathic and allopathic drugs is the result of research (double-blind efficacy studies) needed for the entry of the latter onto the American market. The new drug application process required of allopathic drugs must prove, to the satisfaction of FDA, that these drugs are safe and effective for their labeled claims. Homeopathic drugs do not undergo such rigorous testing. They cannot be patented and, therefore, there is no economic gain to be realized for investing the hundreds of millions of dollars required for research and development of allopathic drugs.

Proponents of homeopathic drugs claim that their effectiveness has been "proved" and that they are effective for their intended uses. Opponents scoff at this and are categorized into three groups. The first group, mainly individuals without a scientific background, is interested in giving them a try. The second group, persons trained in science, are somewhat hesitant because they are accustomed to scientific research leading to a safe and effective association with allopathic drugs. The third group, of course, includes those who say, “Uh, what are you talking about?”

It is worth noting that there has been an upswing in interest in homeopathic medicine, both with lay persons as well as those in pharmacy and medical communities. More advertising is appearing in the lay press and professional journals. FDA recently changed the classification of homeopathic medicines from "fraud and quackery" to "alternative" medicine. Of major importance is a growing feeling that maybe there should not be an "us versus them" attitude between homeopathy and allopathy.

Opinions have been expressed that possibly homeopathic medicine is an integral part of the entire make-up of modern medical practice, and that it should be considered complimentary to allopathy, rather than a totally alternative form of therapy. Factors that are claimed to contribute to the resurgence of homeopathic medicine are listed in Table 2.

Part 2 of this series will discuss the principles of homeopathy, preparation of remedies, and sources and dosage forms of homeopathic remedies.

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What if you suddenly became sick or hurt and lost your ability to earn a living? How would you pay your bills and daily expenses? Surprisingly, one in three working Americans will become disabled for 90 days or more before age 65. One way to protect yourself against the financial loss which would likely result from a disability is to purchase an individual disability income policy, which can provide a monthly income to help pay your living expenses in the event of a disability.

If you are employed by a large company, your employer may provide disability income insurance. However, if your company doesn't provide disability benefits or you're self-employed, it's up to you to make sure you're covered. One option is self-insuring, or keeping a large savings account. However, even if you save 10% of your salary each year, one year of disability could wipe out approximately ten years of savings! You may qualify to receive Social Security Disability benefits; however, Social Security benefits will be, in many cases, less than the amount that would be required to pay your regular living expenses.

What to Do When It's Up to You

A smart method of protecting yourself in the event of a disability is owning an individual disability income policy. There are a few key considerations you should keep in mind when purchasing Disability Income. First, try to purchase a policy that is noncancelable and guaranteed renewable. With this type of policy, the company cannot raise your rates or change your policy as long as you pay your premiums on time. Second, the definition of disability in your policy should be carefully reviewed. The definition of total disability in a policy usually falls into one of two general categories. A more liberal definition tends to define total disability in terms of one's "own" occupation while a less liberal definition tends to require that the individual be unable to work in any occupation.

Third, when deciding upon a policy, you may also wish to consider a few additional features which are often optional. One is residual benefits or partial disability which, under specified circumstances, pays a portion of your benefits if you lose a certain percentage of income due to a disability. This option usually comes into play if you become disabled and are only able to earn a portion of your previous income. Another feature is COLA (Cost of Living Adjustment), which can increase your benefits once a year, after you become disabled. This feature was designed to help protect your benefits against the effects of inflation during a long-term disability. A feature which is especially important is the Guaranteed Insurability provision, which allows you to increase your monthly benefit even if you incur changes in health which would otherwise prevent you from obtaining additional disability coverage. Finally, one of the most important things to do when choosing a disability income policy is to make sure to purchase a policy from a company which has solid financial ratings and offers a flexible enough product to meet your personal needs for quality, value and affordability.

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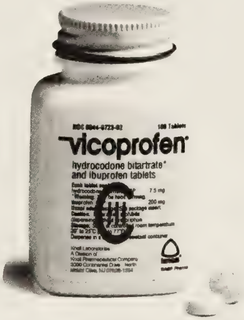

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Continuing Education Quiz

This month's questions are taken from the article on "Patient Counseling on Homeopathy: Part 1: Introduction." Circle your answers to the following questions and mail the entire page to Maryland Pharmacist CE, 650 W. Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members $ 10.00). The completed quiz for this issue must be received by 12/15/99. A continuing education certificate for one and one-half contact hours (0.15 CEU's) will be mailed to you within six to eight weeks. Please type or print clearly. ACPE# 129-144-96-012-H01.

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1. The physician who first expressed the term *homeopathy* in the 1800s was:
   - a. Charles Darwin.
   - b. Samuel Hahnemann.
   - c. William S. Merrell.
   - d. Louis Pasteur.

2. All of the following concepts refer to homeopathy EXCEPT:
   - a. Law of Similars.
   - b. like cures like.
   - c. similar suffering.
   - d. use of enemas and emetics.

3. The Law of Similars is expressed in each of the following ways EXCEPT:
   - a. every substance that causes a pharmacologic effect on healthy humans produces characteristic symptoms.
   - b. every disease causes characteristic symptoms.
   - c. every plant that looks like a human organ is useful in treating disease of that organ.
   - d. every disease can be treated by administering a small homeopathic dose of a substance that causes those same symptoms.

4. Homeopathic dilutions of antigens which induce antibody formation are called:
   - a. allerodes.
   - b. cathodes.
   - c. hominodes.
   - d. isodes.

5. Dilutions of botanical, chemical and zoological substances are called:
   - a. allerodes.
   - b. cathodes.
   - c. hominodes.
   - d. isodes.

6. The process of diluting homeopathic substances to the point they are curative rather than toxic is:
   - a. attenuation.
   - b. potentization.
   - c. succussion.
   - d. trituration.

7. The process of shaking a diluted solution of a homeopathic substance vigorously to increase its energy and remedial properties is called:
   - a. attenuation.
   - b. potentization.
   - c. succussion.
   - d. trituration.

8. The process of vigorously mixing insoluble forms of the homeopathic substance to increase its energy and remedial properties is:
   - a. attentuation.
   - b. potentization.
   - c. succussion.
   - d. trituration.

9. The discovery of all of the following are claimed to have contributed to the decline of homeopathy EXCEPT:
   - a. nitrous oxide for general anesthesia.
   - b. salvarsan for treating syphilis.
   - c. antiseptics for treating wounds.
   - d. cinchona for treating malaria.

10. Homeopathic medicines must meet all the following requirements EXCEPT:
   - a. the Comprehensive Good Manufacturing Practices.
   - b. the package must have an NDC number.
   - c. Tamper Evident Packaging.
   - d. Drug Listing Act.

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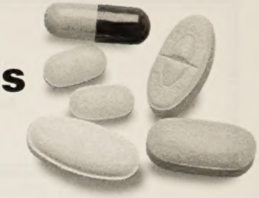

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